HIT Standards Committee Meeting
Final Transcript
August 30, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the 16th meeting of the HIT Standards Committee. This is a federal advisory committee, so there will be opportunity at the end of the call for the public to make comment. It's also a virtual meeting, so just a reminder for the committee members to please mute your phone when you're not talking, and also please don't put us on hold, so we don't hear the hold music. And remember to identify yourselves when speaking.

With that, I'll do a quick roll call. Jonathan Perlin?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anne Castro?

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Aneesh Chopra? Chris Chute? Janet Corrigan?

Janet Corrigan – National Quality Forum – President & CEO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Derr?

John Derr – Golden Living LLC – Chief Technology Strategic Officer
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Carol Diamond will be dialing in late. Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Steve Findlay? Linda Fischetti?

Linda Fischetti – VHA – Chief Health Informatics Officer
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Cita Furlani?

Cita Furlani – NIST – Director
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Martin Harris?

Martin Harris – Cleveland Clinic – Chief Information Officer
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Klimek? David McCallie? Judy Murphy?

Judy Murphy – Aurora Healthcare – Vice President of Applications
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Nancy Orvis? Marc Overhage? Wes Rishel?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, ma'am.

Judy Sparrow – Office of the National Coordinator – Executive Director
Cris Ross? Rick Stephens? Walter Suarez?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Sharon Terry?

Sharon Terry – Genetic Alliance – President & CEO
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Karen Trudel? And Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. With that, I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, Judy and many thanks to everybody. I'd say good morning, and I'll say good morning softly to our West Coast colleagues. It's very early, and thank you in particular for attending this virtual meeting. Although this is a virtual meeting, we have a very robust agenda. Obviously to John Halamka's point, this has not been a summer of relaxation. It's impressive to me to see how much has been accomplished since the inception of this program, but I know that all of you, for which we're most grateful, and our colleagues at the National Coordinator's Office have been burning the midnight and weekend oil.

This is a particularly important time because we've crossed one threshold, and that's the enunciation of the standards in support of meaningful use stage one. But obviously there are some opportunities to consolidate there. There are questions on how one moves from individual systems to the interoperability among systems, really one of the aspirations in terms of a national framework for not only interoperability, but for health information exchange, and more on that in particular in today's call.

And lots of work in terms of the continuing response to the initial and subsequent statutory and regulatory requirements in terms of what we take on, thus I appreciate Sam Karp and working with Aneesh and Farzad to bring us up to date on the enrollment group's work, as well the emerging trust framework that Deven and Paul will continue to share their progress and seek input there. I'm particularly looking forward to Doug Fridsma's discussion because this really is the emerging infrastructure context … standards and interoperability framework that really will help to create a continuity of information interoperability, along with Jamie Ferguson's work on vocabulary that will allow these systems to ultimately exchange information.

For those of us who are working with the challenges in our own environment of trying to bring disparate production systems together, this offers the opportunity for the interoperability, but for those of us who

may be in the position of caring for family members at a distance of personally getting care or providing care to Americans who are mobile, the ability for this care to be informed based on past experience is really fundamentally related to both the standards and interoperability and the vocabulary. And then the real world, the implementation workgroup updates, and again very much appreciative of Judy and Liz's leadership there and then the development of specifications, as well as practical guidance to inform really a policy level approach to standards.

Let me stop there and turn to John Halamka for any introductory comments. Following that, we'll come back and take a look at the minutes from the last meeting. John?

John Halamka – Harvard Medical School – Chief Information Officer
Just two points to highlight: You mentioned that a lot of our work this summer has been follow on to the issue of the financial regulations and final rules, and so what I've tried to do is keep a tally of all the various issues that have come up, and I've circulated them to CMS. I circulated them to Doug Fridsma. My blog this morning reflects on some of the ones that many stakeholders in the community have had confusion about, for example, the C32, as originally constructed. The CCD has specific vocabularies that were required. Those vocabularies were singular. That is, one problem with vocabulary was declared, SNOMED. But yet the final rule allows for options such as ICD-9 and SNOMED.

Well, it turns out, luckily, that the C32 version 2.5 implementation guide, which was the guide included in the final rule, does actually allow for multiple vocabularies for every data element. Although it has a preferred vocabulary of SNOMED, it completely supports ICD-9, so assertions that may have been made that the CCD cannot support all the vocabularies that are delineated in the final rule is actually an incorrect statement, so we're in great shape in that regard. Similarly, statements have been made, such as the quality metrics have specific vocabularies named. Well, in my conversations with Floyd, it turns out that maybe at times shorthand had been used, so a term like RxNorm was placed into the measure when in fact what it really meant was RxNorm, which as in the final rule, can include 11 different vocabularies from Micro Medics to Multum, to First Databank, to Medi Span, etc.

Again, quality metrics are completely consistent with the final rule. And so what I think we can say is if we look at the final rule, even after two months of inspection and questions, it stands very, very well. There's only one small mistake in the final rule, which Doug, I think, will talk to you about today, and that is the implementation guide for syndromic surveillance that is currently listed in the final rule is the incorrect implementation guide, and so ONC is figuring out how best to resolve that. So other than that, should any of you hear from any of your stakeholders in the community about inconsistencies and questions, certainly feel free to forward them to me, and I will be able to work with CMS and ONC, and I'd be happy to serve as sort of the convener and messenger of such issues.

Today's very important discussion will be from Doug Fridsma. All, of course, discussions today are important, but the S&I framework, standards and interoperability framework, is going to be a framework for our work going forward, and we'll hear today about a number of those RFPs that have been awarded to organizations such as Deloitte and Lockheed and Stanley, and so we should understand how the HIT Standards Committee can provide coordination and prioritization of all these various RFP activities that are going on, so I very much look forward to Doug's discussion.

With that, Jonathan, I turn it back to you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right before John spoke, I thought I heard someone who might have been trying to identify they've joined the call.

Alison Gary – Altarum Institute – Communication Technologies Coordinator
This is actually Alison from Altarum. I wish to remind all committee members on the phone, please if you are having any sound coming out of your computer speakers, please mute or turn down your computer speakers. We're receiving feedback and an echo because of that. When you're not speaking, if you could please put your phone on mute, thank you.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
This is David McCallie. I've just joined in a little bit late.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific, David. Thank you for joining.

Cris Ross – LabHub – CIO
This is Cris Ross joining late. Sorry.

Jonathan Perlin – Hospital Corporation of America – CMO & President
With that, I'd ask everybody to take a look at the minutes, and if there are any amplifications, corrections, please mention those. While you're taking a look, again, we'll thank the ONC staff for a very thoughtful synthesis of a very complex discussion. Okay. Hearing none, then let us declare consensus on those minutes and move forward to the body of today's call.

Today we have, to begin with, an update on the enrollment workgroup or from the enrollment workgroup, and I heard Sam Karp join. I don't know if Farzad is on, but I don't believe Aneesh is yet. Sam, I will turn to you to begin this discussion.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Thanks, Jonathan, and good morning, everyone. Aneesh and I, and I think he'll be here shortly, are pleased to be able to update you on the progress of the enrollment workgroup and, more important, to present the workgroup's final recommendations for your approval. You may know these recommendations were presented to the HIT Policy Committee last week on August 19th, and were subsequently approved by that committee.

I want to walk quickly through the first three slides, and then I'll provide a little bit of background and some context before Aneesh and I present the actual recommendations and be prepared to answer any questions that you have. So if you turn to the next slide, slide two, this is a list of the workgroup members, which, in addition to Aneesh, includes two members of this committee, Anne Castro and Cris Ross, both of whom have played key roles in the workgroup. I want to thank both of them.

Move to slide three, slide three is a high level summary of Section 1561 of the Affordable Care Act, which authorized the workgroup and its activities. Let me just read it quickly. No later than 180 days after the enactment of the Affordable Care Act, secretary in consultation with the HIT Policy and Standards Committees shall develop interoperable and secure standards and protocols that facilitate enrollment in federal and state health and human service programs through methods that include providing individuals and authorized third parties notification of eligibility and verification of eligibility. Given the timeline, we have started about 120 days into this charge. The timeline in the statute, and also the time required for federal clearance. We've been on a fast track to develop a set of what we believe are practical recommendations for the administration's consideration and also their action.

Let's go to slide four. This restates the workgroup charge. Basically we've been doing three things: inventorying the standards that are in use, identifying the gaps, and recommending candidate standards, again for federal and state health and human service programs in the following areas: electronic matching for verification of eligibility across state and federal data, retrieval and submission of electronic documentation, the reuse by consumers of their eligibility information, the capability for individuals to manage and maintain their own eligibility information online, and then a process for notifications of eligibility.

Let me just say a few words about our process that brings us to giving you the recommendations today. Since the workgroup first met in May, we've had five meetings. We also mobilized four tiger teams to develop and vet a set of recommendations with the full workgroup. In addition, Doug Frisdma let an internal team of staff and consultants at ONC that looked at the state of data element standardization in state level health and human services programs.

We held two public hearings. We received about 80 written comments to a FACA blog post that Aneesh and I did requesting input, and we held a listening session with state level health and human service representatives to get their feedback on our set of preliminary recommendations.

Why is this all important? I think, as everyone knows, in 2014, nearly 40 million Americans will become newly eligible for coverage under the Affordable Care Act. One of the many challenges that we'll have, and there are many, will be to make the eligibility and enrollment process much more efficient and much more consumer friendly than these processes are today. So recognizing this, the workgroup has developed a set of five underlying principles to guide these recommendations.

Let's go to the next slide. I'm not sure if this slide actually made it in. It's good. Thank you, Judy. These are core principles that we believe are required for a more consumer centric health and human service eligibility and enrollment process. Let me just go through them with you quickly. The first principle is that the process needs to rely on a transparent, understandable, and easy to use online process. The second, it needs to accommodate a range of user capabilities, languages and access considerations, as everybody won't be able to apply online. Third, the process needs to offer seamless integration between private and public insurance options, particularly as individual circumstances change. Fourth, the process needs to connect consumers not only with health coverage, but for those who are eligible also with other human service coverage. SNAP, which is a new name for the food stamp program, or TANF. And last, fifth, the process needs to provide strong privacy and security protections. Again, our recommendations are based largely on these principles.

Let's move to the next slide. I'm going to present the first three of ten recommendations that we have. Then, after each one, take any questions that you have. Then Aneesh will come on, if he is on the call, to present the additional seven recommendations. We have recommendations in four areas.

The first are what we're calling our core data recommendations, and let me read this one to you. We recommend that the federal and state entities administering health and human service programs use the national information exchange model, NIEM guidelines to develop, disseminate, and support standards and processes that enable the consistent, sufficient, and transparent exchange of data elements between programs and states. As I mentioned a moment ago, Doug led a team that did a NIEM analysis of core data elements across 34 programs in 10 states. This was identifying what standards are in place and identifying the gaps.

This process assessed both the complexities of data harmonization and looked at the depth of data harmonization that would be required to accomplish three specific objectives. First, for there to be

consistent understanding of data names, definitions, type, length, and value set. Second, to be able to support mapping of data elements to existing data standards to be able to support interoperability. And third, to support information exchange needed for eligibility verification and the exchange of eligibility information between the insurance exchanges, health plans, and Medicaid programs.

I want to be clear about this first recommendation before I see if there are any questions. We are not requiring or even suggesting that states should change either their core data elements or the way they collect and display those elements within their own system. Rather, what we're proposing is that the NIEM process would insure that those data elements that are already known and common across many of the programs can be transmitted between programs so that the receiving program is able to easily identify and incorporate the data element into its systems.

With that, let me stop and see if there are any questions about this first recommendation. Doug, are you on the line, by the way?

Doug Fridsma – ONC
Yes. I'm here.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Good. Thanks.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So do I understand that this review of data elements led to the verification that it's possible to do this level of exchange without changing the systems in the states?

Sam Karp – California HealthCare Foundation – Chief Program Officer
We believe that it is, as long as what the output of those systems follows the NIEM process, so we have some standards. There's going to be a lot of exchange of data, and there are an awful lot of systems out there, and we don't think it's possible, practical, or is going to happen for those systems to change between now and 2014.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
No dispute on the impractical part. The question was, are they collecting the necessary information they need to provide with the same level of coding and so forth?

Sam Karp – California HealthCare Foundation – Chief Program Officer
I'll let Doug answer that question for you since he did the work, but we're principally talking about core data elements, Wes, so largely we're talking about somewhere between 10 and 12 or 13 core data elements, and I believe that they're all collecting those data elements. What they name them, what the data type isn't necessary consistent. Doug, do you want to answer that?

Doug Fridsma – ONC
For this particular use, to be able to do enrollment eligibility, the kind of data that's required is relatively limited, and so there was pretty good consistency across all of the agencies with regard to the data that was required. I think one of the things that we did realize is that some of them are going to be very, very unique, you know, so we've got things like name and date of birth and social security number that were quite consistent. We probably will get an update from the rule or the business rules folks, and some of the variability across programs have to do probably with the business rules and how the data is reflected that gets collected around that. There are some examples of that as well.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. You get into a situation with the field like —name" where if two different states have a different field length, the state with the shorter length gets truncated, then goes back to the original state and looks like a different name because it's been truncated.

Sam Karp – California HealthCare Foundation – Chief Program Officer
That is the example that we've been using, Wes, particularly when, and you're going to hear in our next set of recommendations. We're talking about verifying eligibility information, income information, etc., with federal sources. And as you know, many of these systems are legacy, some mainframe systems, and changing field length is no simple matter, I've learned. Truncation becomes a problem, and I don't think that those systems 30 years ago anticipated last names being as long as they are today.

Farzad Mostashari – ONC Deputy
I guess what Sam and the workgroup is saying is that the purpose for these standards is not that they impose a requirement that every single source system much change the way they represent their data elements to match the standards, and that the main purpose for this is to provide a clear understanding of what the data definitions are and how they are to be transported between systems that could then be used. It could be maps. It could be incorporated systems.

You're absolutely right that we have not done an analysis that concludes categorically that no source system would need to make any modifications in order to make ideal use of the information once communicated. So that's the distinction I want to draw is between the purpose of the standards versus affirmative knowledge that no source system may have to make any changes at all.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So if I was to restate that, you have options going forward of providing less functionality sooner by limiting the uses, but you have not determined yet what would be the full impact to get to all of the uses that might be handy.

Farzad Mostashari – ONC Deputy
Again, there's local autonomy in deciding what uses may be handy for them and to what extent the risks and benefits outweigh the costs for them of modifying the systems.

M
Any other questions for Sam?

Sam Karp – California HealthCare Foundation – Chief Program Officer
Let me then move to the second recommendation, and move to the next slide, please. This is the first of two verification interface recommendations. I'll just read quickly recommendation 2.1.

We recommend that federal agencies required by Section 14.11 of the Affordable Care Act, which I'll go back and talk about, to share data with states and other entities for verification of an individual's initial eligibility, recertification, and change in circumstances for ACA health insurance coverage options, including Medicaid and CHIP, use a set of standardized Web services that could also be used to support such eligibility determinations in other health and human service programs such as SNAP and TANF. And then phrase below, to accomplish this recommendation, federal and state agencies should provide data by individual as opposed to households to insure that data can be used in a consumer-mediated approach.

Section 14.11 of the Affordable Care Act requires three electronic verifications for eligibility. The first is to the IRS to verify income. The second is to the Social Security Administration to verify citizenship. The third is to the Department of Homeland Security to verify legal status.

We, in one our public hearings, had representatives from each of those federal agencies discuss with us their plans to be able to develop a Web services interface that could operate in real time and provide these services. The department of Social Security Administration actually has a pilot program currently running with 26 states where, in a batch mode, they provide citizenship verification, have about a 94% match rate, and they've already developed a real time capability to supercede their batch program, which they're testing. And they have said to us that one of the critical things is standardization of the data elements, and I think, in most of these cases, there are only four or five data elements that are used to drive the match, and that standardization of those data elements would increase the match rate, so that's the first.

Let me do the second recommendation, and then we'll go back and discuss both of these. Recommendation 2.2 is that we recommend development of a federal reference software model implementing standards for obtaining verification of an individual's initial eligibility, recertification, change in circumstance information from federal and state agencies to insure a consistent, cost effective, and streamlined approach across programs, states, and community partners. Now while the initial build of this toolset should include interfaces to the three federal agencies that I just reviewed, in order to insure comprehensive and timely verification, there are additional interfaces to federal, state, or other widely available data sources and tools that we believe should be added to this verification reference software model. Then we go on to list the various additional federal and state services, including the U.S. Postal Service, which has an address standardization API that could be used.

Our first recommendation is that to meet the federal requirement for electronic verification to the three primary sources of information that a Web service standardized Web service to use. The second recommendation is so that this doesn't necessarily have to be built 50+ times. That the federal government develops a reference software model that potentially could be used or at least the specifications could be used by states. Let me stop with that and answer any questions you have.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, it's always the same old hands.

M
Go ahead, Wes.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Wes, I've been answering these questions for ten years with you now.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. And maybe in another— Never mind. So we have a lot of experience with this, with the NHIN Direct project. As I think about what's different here, I don't think the differences argue against the success of building this toolset. But they do suggest some differences in the approach.

Probably it's no surprise to anybody that the policy and privacy issues will make the DURSA look small. But as far as the tooling, a key aspect of this tooling is that it work with legacy systems, and most of what's done now in Code-a-Thons and building reference things is based on Java, .NET, and all that snazzy stuff. As you put together this committee, it's important that you figure out how to represent the

legacy system implementers, finding those who are … motivated to participate, and yet understand the issues.

Sam Karp – California HealthCare Foundation – Chief Program Officer
I think that's important, and it's not hard to find them. They're everywhere.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's good.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Right? Since most of these systems in states are these legacy systems. One thing I should point out is that depending on how states implement the exchanges that are called for in the Affordable Care Act, and states, as you know, have an option to develop their own exchange or to use a federal exchange. We see that potentially new system being developed, certainly in many of the large states will have the ability to more easily interface with the kind of service that we're talking about. But you raise, I think, the right question about the task and challenge there'll be for the legacy systems to communicate with the Web service. Many are doing it today, which is the way they've been able to maintain their systems, so that will be an issue.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. And just to clarify, you're talking about the other HIE, right, the health insurance exchange?

Sam Karp – California HealthCare Foundation – Chief Program Officer
That's right. The other HIE. That's exactly right. And you raise the privacy issues, which we'll address in our last set of recommendations, but clearly consumer consent, limitation of use, which we'll talk about, are key components of the privacy and security policies that would help govern this.

Farzad Mostashari – ONC Deputy
Wes, similar to NHIN Direct or NHIN Connect projects, the end result of this is not … the goal for this is to have a reference implementation in software that could be used either as a reference for other people who want to build—unambiguously represent the standards so that people can build it into their own system, or potentially used as modules for people to incorporate into their systems or add onto their systems. But it is importantly not meant to be—what this recommendation is not calling for is that there actually be a service, a federal service, a hub through which everything flows. The first recommendation deals with the federal agencies responsible for responding to verification requests that they provide Web services, but they own those services. This is just a piece of software that can help access those verification services and potentially others in an accessible way.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Good. If there are no other questions, we'll move on. Aneesh, have you joined?

Aneesh Chopra – White House – CTO
I am.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Good. Hand off to you, brother.

Aneesh Chopra – White House – CTO
Thank you very much, Sam. I appreciate it. To my colleagues on the standards committee, it's a pleasure to join on yet another wonderful occasion. What I'd like to do is walk through the last set of

recommendations in three parts: a discussion on business rules, how we transmit the enrollment information, and then obviously the big set of recommendations on privacy and security. So let's start with business rules. I'm presuming we're now on the right slide. There are two key recommendations to share.

The first, I might reference as the transparency recommendation, and that basically is a call for federal and state agencies to express their business rules in a consistent, technology neutral standard, and ideally that they should be made available in clear and – they should be clearly and unambiguously expressed, ideally outside of the transactional systems for all the reasons Wes has outlined. From my state experience in the commonwealth, these, to try to find the rules buried into these systems built in Unisys Mapper, not the easiest process. So we're trying to make it very clear that the rules themselves should be ideally outside of those transactional systems in the transparency provision.

The second of the two recommendations is that there should be some mechanism for an open and collaborative exchange of the information and hopefully a platform for innovation. What that means specifically is that we want the federal government to have some type of repository of these business rules that might be available specifically on those that are needed to administer the ACA health insurance program coverage options with a particular emphasis on Medicaid and CHIP. In other words, starting, there's a whole suite of activities spanning all health and human service programs. And what this recommendation tries to do is sort of prioritize the insurance components first and to make that information available both to individuals and, more importantly, to developers who can build systems that are standards based and also available in human readable format.

Then, over time, we would move to the broader set of health and human service programs that were called for like SNAP and TANF. Those are the two key recommendations on business rules, and we had a lot of wonderful debate on this set of topics during the course of the committee. The appendices for these reports are going to have a lot more of that color, but would take any questions the group might have on business rules first. Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I was trying not to be the same old hand here. This is wonderful and, in my view, certainly at the leading edge of standardization, I think we learned with the HIPAA transaction regulations and learning again with ICD-10, the business logic is not externally documented and very few people actually understand what it is. So the ability to prepare that standard representation of the business rules will be a challenge for your constituents, particularly if you're looking for it to happen quickly. The best I think they can do is some approximation, as long as you keep it simple.

Aneesh Chopra – White House – CTO
Well, this came up in great lengths over the course of the review period, and particularly around issues around how do you define income. You know, some states adjusted for X, Y, or Z purposes. And so the developer question was to the extent that that information could be accessible, that would make it a lot – obviously that's the whole purpose here and the Holly Grail.

I think the repository will start to create some reusability of these rules and, frankly, might bring down some of the burden on going forward development activity. In fact, I think a lot of this is going to have a benefit on the go forward side. A lot of the states and localities that were involved or giving testimony sort of talked about this might give them the roadmap, if you will, as they build and modify their core systems to sort of start to get this stuff liberated. Again, the repository then could be the mechanism to help on the implementation costs, as states move forward. So a lot of moving pieces in this set, but I think, principally, our whole point is I think these are the right principles going forward.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
At the risk of violently agreeing with you, I really think that this has been the missing piece, and standardization is some way of sharing business rules that's effective. I just think that the challenges are substantial, and that sort of the implementation group principles of trying to achieve a little bit and set a direction will be critical here.

Aneesh Chopra – White House – CTO
Are there others in the group keen on this particular set of topic areas?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
A question about the thoughts about tooling and complexity, if we have the NIEM managing the data element definitions and the business rules in a different format or a different system, some of these that you list don't even really have tools available yet.

Aneesh Chopra – White House – CTO
Correct.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
How do those relate back and forth to each other? It's a pretty technical, low-level detail maybe not yet worked out. But we could end up with multiple, independent repositories each containing part of the necessary information.

Aneesh Chopra – White House – CTO
The core data elements are a bit more binary. These have the challenge of trying to express sort of policy ideas in ways that there really isn't a lot of clarity on how to do this. I mean, if there was any obvious point to this review cycle, it's that we haven't really developed a common language. We joked earlier, I think, even with Wes on the phone at one point, about how ardent syntax had kind of attempted this, and we're king of at that same point in terms of trying to find an answer.

I don't know, and actually it's a good question for Doug, if the NIEM framework could actually apply in the context of business rules. I don't believe that we've used it that way or thought of it that way. Doug, do you want to react?

Doug Fridsma – ONC
One of the things that we have in looking at the NIEM process is that it's very good on data, but I think you're absolutely right that it doesn't capture kind of the behavioral aspects, which are the business rules and the services and sort of the other, the things that you do with the data. So one of the things that we've been working really hard is extending the functionality within the NIEM process to capture not only kind of harmonization or making unambiguous the data, but also working at describing in an unambiguous way the services that are there and the behavioral aspects of which the business rules are going to be a part.

Cris Ross – LabHub – CIO
On the business rules tiger team, we looked at that issue a lot, David, and also the issues that Wes alluded to. The core view is that business rules can't exist abstract from a data domain and that the expectation would be that the business rules description would have a clear, cross-representation to the data model. The challenge that we ran into is if the data model was fully articulated and consistent across all states, if the program rules were consistent across all states, and the deployment architecture was the same, we wouldn't need business rules, but this would also be a really easy problem.

I know I'm sort of preaching to the choir or lecturing to the professor, but what we were trying to do was to come across with the idea of, you know, how do you document rules once for deployment everywhere where relevant. And so we talked to an awful lot of experts about this, and the belief was that to document the rules, you know, according to recommendation one, and in an abstract business oriented way. Then the second was to try to create a mechanism for deploying those rules with variations, as appropriate, was really the only way we could handle it. There is a lot of nuance in the appendix on this topic because it's clearly pretty complicated.

I'd also add to Wes' comment. The issue about extracting business rule and documenting is obviously enormous. We heard from folks that there are some methods for extracting business rules, and that people who do this all the time discover that people have working systems that actually function different than the way they expect that they do. But I think our recommendation really was to focus on the representation of the rules that are unique to ACA, and if states want to use this repository mechanism to dig deeper into their infrastructure of systems, have at it. That's really the intent to see what would happen if states began to collaborate.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It'd be an interesting question to know if you end up with a dozen business rules or 200 business rules. I'm certainly hoping for a dozen.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
My fear would be that you'd end up with 200 simply because the predicates would be slightly different and, therefore, they're different rules. And that ties you back to these data element harmonizations, if they don't agree. I mean, the two problems aren't easy to separate, as everyone knows. I'm not saying anything new here.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That is the lesson of the ardent syntax.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Exactly. I think that is a great analogy because it's exactly what you run into.

Cris Ross – LabHub – CIO
The slight difference though is that ardent gets pretty close to an implementation language as opposed to a documentation of the rules in an abstract, reusable fashion. So rules branch, so I think we should expect to see 20 rules that program administrators and advocates and consumers would be aware of, and we would probably have 200 rules that implement them. And then we'd probably have 2,000 sorts of node rules that deal with local particularities and exceptions and how to handle some of the utility class kinds of activities.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Everything is complex to a level that we don't realize that is complex until we try to make it simple.

Cris Ross – LabHub – CIO
Or document it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, right. I think that any process that brings everyone to have to state their business rules in a way that's understandable to other people is good. I hope that this will seek to—I mean, a common example

right now is you take notebooks that represent cancer protocols and try to put them into computers, and they turn out they have as many ambiguities as the Panama Canal Treaty, and I hope we find a way to sort of identify the inconsistencies that are glossing over actual differences and bring them to the surface. Otherwise we won't have accomplished that much.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
If you go to the trouble of actually encoding even your abstract business rules in a fairly complex and somewhat archae syntax like RIF, which uses RDF, NL, and all these things that are not human readable, what have you accomplished? If it's not human readable, but it's not executable either, is it worth all the trouble?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Good point.

Cris Ross – LabHub – CIO
Well, I guess a couple things, one of which is SBVR is the one that's stepped above that that's probably more human readable.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Good. I don't know anything about that one, so I'm speaking from ignorance as much as ….

Cris Ross – LabHub – CIO
No, David. Your point is absolutely superb. We really went around and around on this issue. I think we were going in a direction; we weren't just spinning. But to the question of what good is it, the issue is that if we're trying to develop a system that's suitable for deployment into a Unisys Mapper system into some new .NET or Java thing, something that's written on legacy COBOL that's maybe been updated to Object COBOL. You know, you've got all these deployment environments trying to express the rules in a deployment flavor would mean that you'd have almost infinite variations when you layer on top of that variations in program and variations from state-to-state.

So it's really hard work, and the smartest people that we talk to about this said, you know, there's no avoiding doing hard work. Someone needs to do this abstraction that then can be reused in lots of environments. In order to achieve that goal, it means you need to be incredibly precise around your descriptions. And whoever is going to organize this activity within HHS has a big job on their hands. There's no question about it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's the great part of working on committees is you get to say, whoever is going to do this.

Aneesh Chopra – White House – CTO
…some of us are on the other side of that one.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think what I understand now that I didn't understand at the start of this discussion is that the goal is to create comparability of business rules for people rather than to create an implementation language for implementation for—pardon me, but implementation … implementation rules. But that's clearly an easier goal to get started. I'd like to see this continue beyond that at some point.

Cris Ross – LabHub – CIO

Yes. The analogy is the airlines have these incredibly complicated rules to make sure that the planes run and that they're full of maximum paying passengers. And when those rules sometimes get exposed to us consumers, it's incredibly annoying and frustrating. We want rules for can I exchange my ticket, and what will it cost me? And what are my choices to get from here to Albuquerque? So this rule set needs to support both purposes. It needs to support a developer who is building this intense revenue maximization system for an airline, my analogy, as well as help passengers understand what their choices are so they can choose the right flight.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks to certain federal committees, I've gotten higher on the mileage chain than I used to be, and I find that those airline systems work by having an—because the supervisor has the authority to override the computer.

Aneesh Chopra – White House – CTO
All right. Business rules, complex, but important, let's move on to transmission. This was an important component of the effort in that this was not simply about the government, federal, state, and/or local systems doing the initial eligibility checking, but the actual fulfillment of the enrollment process. And so we included recommendations explicitly on how to transmit the applicant eligibility, enrollment, and disenrollment information in a two-way model between the insurance programs, public and private, the coverage options, and so forth and so on, and these, whether it be the health insurance exchange or these other entities.

The committee's first recommendation was to use the existing HIPAA standards, 834, 270, and 271, as the method of transmission. And then there was a slight adjustment with the recommendation 4.2, which was that further investigation would be necessary into whether or not the standards allow for the acknowledgement of a health plan's receipt of a HIPAA 834 transaction and, if necessary, to recommend the development of new standards for that purpose.

Any questions on these relatively straightforward recommendations or thoughts, if anyone knows how to solve 4.2? Anyone else on the line, Carol, anyone? Hello? Hello? Buehler?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I'm here, but I have nothing to add to this.

Aneesh Chopra – White House – CTO
Any other questions on this one, or should we move to the privacy committee?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes. Just one. Wes probably already knows this, but I've been, I'm trying to figure out all the work we did on standardizing the enrollment and healthcare enrollment customer, beneficiary demographics, marital status, gender, whatever. Is there still any contention or resolution that has to be done on those key kinds of code sets like for identifying a person in order for these business rules to work, or is that all resolved at this point?

Aneesh Chopra – White House – CTO
The committee that looked into that issue basically felt the current standards are sufficient with one exception, and that is the acknowledgement of the receipt of the message. Farzad, any reaction you want to complement that with?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

I'm talking about the underlying core data model for this reference software.

Farzad Mostashari – ONC Deputy
Yes. I think it's more attached to the earlier discussion.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes.

Farzad Mostashari – ONC Deputy
Yes. It is important in order to have the basic business rules applied consistently to have a first step common understanding of the definitions. And, for some, it's easier, although not without complexity, even some things that might seem at first blush relatively simple like, I don't know, citizenship for example.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Let's take marital status. That's my favorite one.

Farzad Mostashari – ONC Deputy
Yes. That can have complexities, and for some, like income or household composition, which are critical, there's actually a great deal of complexity in terms of how they're represented, so the group has done some pretty thorough analysis of those differences, and we'll have some recommendations in terms of at the data elements and data definition level so that we remove ambiguity in terms of what exactly it is that we're talking about in which the business rules then get applied to.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I don't think you answered my question, but I think my simple question was, given the work the health IT standards panel did, and supposedly what the standards coordinating organization, which was the group of all the ANSI groups, you know, of eight of them together, is there still the marital status and code sets and value sets that have to be resolved among the states, or is that basically done? That's my question.

Farzad Mostashari – ONC Deputy
I think that's an important issue, and that work is not done at this point.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
It's the thorny thing. I've been looking at this for ten years, and that's one of the key things. If we still are not compatible on what the unified set will be or how to interpret those sets coming in from different states and counties, to me that's some of the hardest work still to do because you can't have common business rules if you can't figure out what the data is from everybody.

I think your recommendation 4.2 needs to be stronger than just we recommend further investigation of existing standards. Even on the data in the early ones, you need to say, there needs to be continued work to harmonize and come to agreement. I think it may not be on 4.2. It may be on one of your earlier recommendations.

John Halamka – Harvard Medical School – Chief Information Officer
With marital status, yes, there's additional work. Gender is largely done with the work that has been done by HITSP and the coordinating standards committee, as you described. And CAQH Core has certainly put together a whole variety of code sets and vocabularies.

Jamie, from your perspective as the vocabulary taskforce publishes its code sets, anything else you would add?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No. I mean, I think we're going to have to look at these requirements, if there are similar ones. This is not something that we really have addressed yet.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Okay.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I think that this is a fairly strong recommendation regarding the enrollment because of the priority on private health payers and Medicaid. It's going to be an issue when we move to TANF and SNAP and other health and human service programs. But today, Medicaid uses the 834 and the private payers use 834.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
On this slide, I'm sort of having a disconnect between the prior statement that we use Web services and the statement here that we'll use the X12 transmissions because there's technical issues sending X12 using Web services. Is that part of the plan here? I don't know. Maybe HITSP has already addressed it, for all I know.

Aneesh Chopra – White House – CTO
Wes, let me just separate the two recommendations. On verification interfaces, the notion was that if you were to make a call into Social Security that they should respond or accept based on Web services. As to the handoff between a state insurance exchange and BlueCross of South Carolina, since there exists a standard that's in use, and it's working, the recommendation was to maintain and continue on that with the one exception of the receipt.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
And I believe I've done some further research, and there is an acknowledgement.

Aneesh Chopra – White House – CTO
There is an acknowledgement. Good.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
There's been a whole lot of work done on acknowledgement, I know. I don't know that it's risen to the level of a HIPAA standard recognized by the secretary, but it's a critical piece. With that clarification, this makes a whole lot of sense. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
There's also, Wes, a lot of implementation guides, whether that's CAQH, NEHEN in Massachusetts, have separated the content standards of 834 and 270 and 271 from the transmission standards of SOAP or REST or other approaches. So I think, as Aneesh has said, we will make it work with existing transmission standards where the transaction is already in process. But I don't think that the use of Web services with 834 or 270 or 271 is out of the question. It certainly could be consistent with.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It's just work that needs to be done is all.

John Halamka – Harvard Medical School – Chief Information Officer
Right.

Aneesh Chopra – White House – CTO
Let's move on to the privacy and security recommendations, and here I think we're going to see harmonization between all of the tiger teams that have been underway over the last couple of months. Here are the core recommendations that came out of it. The first piece was that we strongly recommended that consumers have timely, electronic access to their eligibility enrollment data in a format that they can use and reuse.

We recommended that they should have the knowledge of how their eligibility and enrollment information will be used, including the sharing across programs to facilitate additional enrollments and, frankly, we wanted them to have control over such uses to the extent practicable. Then the third component of that recommendation was the ability to request a correction or update that information: change of circumstance, a job, a loss of job, and so forth. Absolutely this recommendation is built on all of the great work that frankly our illustrious team has worked on in the context of the HITECH Act, so this is really a replay back to the group, so in great thinking here, but to apply it in the administrative context.

Let me do the other two briefly, and we can come back to the full set for questions. The next slide is the second recommendation, and that is that we recommend the consumer's ability to designate third party access be as specific as feasible regarding authorization to data, whether it be for read only, write only, read/write, or all those permutations, access to data types and functions and role permissions and so forth. If third party access is allowed, and again, those are policy decisions, but from the technology and privacy and security standpoint, if the access is allowed, it should be subject to the granting of separate authentication and/or login processes for third parties. There should be immutable audit logs designating for each specific proxy access and for major activities, and that the information should be time limited and easily revocable.

Here we got a lot of insight around how a third party, whether it be organizations or software systems or what have you, can actually help enhance controls for, in this case, the consumer's very pertinent information when it comes to thinking about that one stop shopping feeling where you have data entered once and then reused, but with full control by the individual or the third party that's working on their behalf. We might want to come back to that recommendation for discussion, which is a very thoughtful and rich discussion in the committee.

I'll come back to the third recommendation now in the last slide for our group, and that is that we recommend that state or other entities that are administering health and human service programs implement strong security safeguards to insure the privacy and security of PII, and we specifically highlighted the importance of encrypting data in motion, referencing the NIST framework, and that automated eligibility systems should have the capability to record actions related to PII for determining eligibility, and also should be available for the purposes of an audit log. Those are the recommendations on privacy and security, and would welcome a healthy discussion here if there is interest.

Kevin Hutchinson – Prematics, Inc. – CEO
On the privacy and security, under the third party access, are we being clear for not only these committee members, but also the public in general, as to what we're defining as third party? For example, would a provider of medical care be considered a third party?

Aneesh Chopra – White House – CTO

Well, the definition of third party for proxy was sort of an interesting one that took place over the last couple of weeks. Maybe it's not as clear, and we tried to clear it. Maybe we made it less clear. But basically this is meant to describe in technical terms a separately—so let's say a nonprofit organization had a software package that would help advocate on your behalf to insure you're getting all that you're entitled to as a party to these various programs. That software application, what we're saying is, should be separately authenticated and maintained as an asset, as opposed to simply the alternative, which would be, give me your login and password, and we'll kind of do it on your behalf where you don't really know who actually is doing the work, if it's someone logged in as you or if it's you.

So we talked a lot about technical standards like OAUTH and how Netflix uses OAUTH as an example was sort of an easy one for people to grasp in the discussion, so that's where that came from. We tried to make it clear. Sam, do you want to react to the clarity issue?

Sam Karp – California HealthCare Foundation – Chief Program Officer
I think it isn't as clear as it needs to be. I first agree with that. We're largely talking about family members or an assister at a community based organization that's helping a consumer complete an application. Those are the kinds of use cases that we see more often.

Paul Egerman – eScription – CEO
What you said, Sam, is correct. But to answer the question, there are some cases where the provider could be one of these third parties, so a common situation is a patient is seen in an emergency department. And, in the emergency department, they actually enroll the patient in Medicaid.

Sam Karp – California HealthCare Foundation – Chief Program Officer
Yes.

Paul Egerman – eScription – CEO
That would be a situation where this third party access rules would apply, so you still want separate authentication or separate logons for that emergency department individual who is performing that function.

Kevin Hutchinson – Prematics, Inc. – CEO
That's helpful. Thank you.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I guess I would ask, isn't it possible though that it's also the kind of service that Aneesh was alluding to, which is a third party service that's being provided through software to sort of help the consumer enroll? The reason I ask about that is because it seems like these recommendations address some of the FIPs, but not all, and some additional Fair Information Principles to consider are sort of use limitations and collection limitation, which is, if there's a third party that has access to the consumer's enrollment data as a function of performing this service that there be limitations on the ways that they can use that information.

Aneesh Chopra – White House – CTO
…came up.

Paul Egerman – eScription – CEO
Excellent comment, Carol. Deven brought up the exact same issue in the policy committee meeting. In the final letter, it was very clearly written there would be collection and use limitations.

Aneesh Chopra – White House – CTO
Yes.

Farzad Mostashari – ONC Deputy
They're in the appendix, and we'll discuss at the end the process for review of the appendices.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I see, so these recommendations will be revised. Is that…?

Farzad Mostashari – ONC Deputy
The recommendations, we hope, will be approved with any particular—no line edits have come up so far, but any line edits that do arise, and then we will follow this with providing the supporting material that's going to be contained in the appendices by e-mail for your review and hopefully approval. So the Appendix F deals with privacy and security. It describes the requirements around, for example, Fair Information Practices and consumer-mediated approach.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. I guess I would just want to make sure that however the recommendation gets written, that there's a clear signal that the use of that information, if it's collected to help the consumer perform that function is, well, the purpose for its collection and the use is limited.

Paul Egerman – eScription – CEO
Good point.

Sam Karp – California HealthCare Foundation – Chief Program Officer
We agree, Carol. When we had, for example, the three federal agencies in, we asked each of them about their limitation of use, provisions in existing agreements that they have for these verification services as well.

Farzad Mostashari – ONC Deputy
And they all have, yes.

Sam Karp – California HealthCare Foundation – Chief Program Officer
They all have. In fact, I even asked Deven to look at one of them just to get her sense of it, and she thought they were all current, the ones she looked at.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Good.

Aneesh Chopra – White House – CTO
Any other reactions? With that, Farzad, would you like to describe what you already did on what the appendices will look like and how we'll move this process forward?

Farzad Mostashari – ONC Deputy
Sure. We hope to be … a very tight timeline … require 180 days, which ends September 17th. We do have to move this through the recommendations, once received at HHS, also through our internal clearance process to determine whether the recommendations will be accepted in full or in part, and then promulgated by the secretary for states to use in various implementations, as those develop over time.

We recognize that this is going to an iterative process, particularly on the data elements we've heard and business rules and so forth. We are far from being able to give kind of the definitive implementation specifications, for example, that we would like to have and that we'll need to have, so we are viewing this as an ongoing piece of work, but these initial set of recommendations should, that we've heard today, we hope will be approved. What goes along with them are a set of appendices, one to two pages each, that go into more detail and provide more color for the recommendations.

Of particular interest, I think, to the standards committee will be Appendix B, which is about the core data elements, and I think some of the discussions that we've had are going to be highly relevant to that. What we hope to accomplish in this first go around is agreements on what the core data elements are and what their definitions are, and we will have, in the future, hopefully the next turn of the crank, we will have the implementation specifications that provide some of the detail that will be necessary to follow.

Doug, do you want to say anything about how this is going to go forward on the data elements side?

Doug Fridsma – ONC
The appendix, I don't think that those have been distributed yet, but we will follow the process that Farzad has sort of articulated here in the sense that we'll distribute that via e-mail and hope to get comments back on that. One of the things that within the analysis, and we've presented some of this within the last couple of weeks, our real focus is going to be looking at the data elements that have data elements that have been identified and the definitions that correspond to them, realizing that about a third of them are pretty easy to look at in terms of consistency across various agencies. There's a third that will likely need just a little bit of work to make sure that we have clarity, and then another third that's going to require the kind of work that's been discussed here, making sure that we have an understanding of not only the data elements, but their associated business rules. And so we'll be distributing those and hopefully be getting some comments back as well.

Farzad Mostashari – ONC Deputy
It will be a pretty tight timeframe, unfortunately, in terms of being able to turn those around, so we can meet the deadline. But thank you for your continued support.

Aneesh Chopra – White House – CTO
Does anyone have any diverging views on the actual core recommendations themselves worthy of line edits that they'd like to share, or would you like to move forward on some type of approval process, Mr. Perlin?

Rick Stephens – Boeing – Senior VP HR
This is Rick Stephens. I don't have any edits to the recommendations. The one question that's in my mind though, particularly as it relates to the business side, eligibility, am I eligible to receive healthcare is one element? But that's going to be also an indication of, as people shop around relative to the cost, and I've heard nothing in here about what the cost associated is, assuming I'm eligible. And, as we all know, depending upon what our personal health circumstances are, what our income is, all those elements play into cost. I can't help but believe somehow that's got to get into this equation.

Farzad Mostashari – ONC Deputy
I think that the work in this, again, this is going to be an ongoing process. I think the first turn of the crank was really getting the basics down in terms of the eligibility. That was kind of the task, what we were tasked with in 1561, and I have no doubt that those are the kinds of issues that will come around with successful turns of the crank, particularly as these systems on the exchange side get more fully—the policy issues around those get more fully realized.

John Halamka – Harvard Medical School – Chief Information Officer
Okay. So we have … presentation. Were you going to say something?

M
No comments from me.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I was going to suggest a potential line edit. Recommendation 3.1, which is about business rules, after the first sentence ends in a long parenthetical phrase, I would suggest consistent with data standards developed under other recommendations.

Farzad Mostashari – ONC Deputy
What is the …?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
We had a long discussion on the difficulty in expressing business rules in the abstract, in a way that's uncoordinated with data, data standards, so I think recommendation 2.1 ….

Farzad Mostashari – ONC Deputy
So you're saying make the connection. Right, make a connection between 3.1 and 1.1 around the core data elements.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Right.

Farzad Mostashari – ONC Deputy
Okay.

M
…disconnecting them?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I like that as well.

Aneesh Chopra – White House – CTO
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Other recommendations?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm trying to understand. On the backend, you know, you have people entering all this information about their eligibility, and then it comes back and says, yes … you're eligible for insurance. Pick from the following. The person picks something. I'm concerned about the persistence and the access to the information that goes into the system. Once there are approved or eligible, determined eligible for coverage, do all of the data that they've entered into the system persist? That's one question. The other question is who has access to that massive data that's in the system upon which these decisions are made?

Farzad Mostashari – ONC Deputy
I can ask Sam also to comment. This set of recommendations in terms of the standards can be applied in a variety of different implementations … and it could be that these are state systems that are accepting the applications where they're existing or potentially new policies could be in place around their retention of the record. It could also be that these standards are used by third parties, nonprofits for example, who may facilitate the enrollment process.

Again, there are going to be a set of policies around those kinds of programs and, I'm sure, agreements that would have to be articulated in terms of those data retention policies. We are stating here is that while the overall goal of this whole this is actually to … information be able to be reused. That is the goal that is the good that comes from this. But it needs to be done with full transparency and with purpose specification use limitations in accordance with the Fair Information Practices. Dixie, I think these are really important policy issues, but I think it would be hard for us to answer them categorically at this time.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would like to see some reference to Fair Information Practices in the recommendation. Even though you've addressed in 5.1 the provision of transparency to consumers, etc., I think that it's important also that the Fair Information Practices be recommended as part of what you take forward.

Farzad Mostashari – ONC Deputy
That's a good point. I'm wondering if we can't alter recommendation 5.3. Dixie, did you have any particular places where—? I mean, we could also make it as the front part of 5.1.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I would expand 5.1.

Farzad Mostashari – ONC Deputy
Yes. Maybe we'd start off by talking about Fair Information Practices and have the three specifics be an outgrowth of Fair Information Practices rather than standing alone.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, and I would add the fourth of secondary use of the data.

Farzad Mostashari – ONC Deputy
I think that's captured in two.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't. Not as you've described third parties here because you've described, and I think Keith asked the question, you know, the definition of third parties, and what I understood to be your answer was that third parties are individuals and entities that really representing the consumer, not third parties with interests of their own.

Farzad Mostashari – ONC Deputy
That's correct.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
It belongs in 5.1, and I think that it should be expanded to include that.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I might suggest it would be a very organizing thing if all of the privacy and security recommendations that come from all the various committees sort of get organized in the context of the ONC framework, which is the Fair Information Practices and sort of goes through each of the principles, and then recommendations sort of fall under there. It's a trick for all the different committees who might have to address privacy and security issues to make sure that the approach is holistic and addresses all of the principles.

Farzad Mostashari – ONC Deputy
That's fair. So we could actually so in terms of the practical edits, what this might translate into is having kind of a section as the header to the privacy and security recommendations that talks about the overall privacy and security framework and the Fair Information Practices prior to each of the recommendations.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. That's good. Thank you.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. It's a good process too, just for sort of, you know, checking on yourself.

M
Well, and I like the consistency across all the different issues that will come up that have the same framework.

M
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Good comments. Unless there are any other recommended line edits, let me ask if anyone has objections or a committee consensus to moving this forward. Hearing none, Aneesh, I think your question is answered, and many thanks to you, Farzad, and to Sam for just terrific work. Obviously this will be a discussion that continues. I think the points that were just raised in the final discussion around the line edits and information fair use are very good and really provide an ongoing segue with the work of the tiger team.

With that, we will turn to Deven and Paul to bring us up to date on your most recent work, and many thanks to the very thoughtful document outlining a number of important recommendations.

Deven McGraw – Center for Democracy & Technology – Director
Terrific. Thanks very much, John. Can everyone hear me okay?

M
Yes.

M
Deven McGraw – Center for Democracy & Technology – Director
Terrific. … presentation that we gave to the policy committee on the 19th, which was accepted without modification, and so we're going to present essentially the same presentation to you all today. We've been presenting sort of bits and pieces of it. It's the culmination of all of our work over the summer, and you've seen bits and pieces of it in your previous meetings, and we've taken your feedback and incorporated it into what was our final set of recommendations.

I know that all of you got the letter, which is really the comprehensive set of our recommendations. These slides are really just a snapshot, but enable us to focus on and highlight for you some of the more salient recommendations. Again, to really get the full picture, you should read the letter, which I hope all of you have had a chance to do.

I want to start off by thanking the members of the tiger team who worked very hard over the summer, quite often two calls a week at three to four hours a pop, so getting to this place was definitely not easy, and we would not have been able to do it without a lot of sacrifice from the people you see listed here, many of whom are members of the standards committee. Again, my thanks.

I'll pause for a second and let my cochair add his thanks as well. We just wouldn't be here, and also we've underlined the names of the staff who provided us with a very high degree of assistance. Adam Greene from the Office of Civil Rights, Joy Pritts, the chief privacy officer at ONC, and then of course Judy Sparrow, without whom we wouldn't be able to function.

Paul Egerman – eScription – CEO
Yes. I just wanted to echo what Deven just said. Dr. Halamka earlier this morning made a comment about summertime, and we worked these people very, very hard over the summer, and very much appreciate their dedication. Specifically, the four members of the standards committee, Dixie Baker, Carol Diamond, David McCallie, Wes Rishel, really did terrific work and had a major, major impact and major influence on the results, so most appreciate the dedication.

Deven McGraw – Center for Democracy & Technology – Director
With that, we'll jump right in to the presentation. Here's the agenda that will follow today. Essentially we're going to review the recommendation letter again, but focused more particularly on some items that are new. But here's the general order of the presentation. We're going to reinforce what the scope of our recommendations cover. It's not all exchange under the sun, but is in fact a smaller universe. There's much more work to be done on issues that we did not get to over the summer.

We have a core recommendation, which is really an overarching one involving Fair Information Practices, a theme that's been very present in your conversations here today, some core values that are really the foundation for our recommendations and, in particular, those involving an individual's right to consent, to data exchange for treatment purposes. What are the triggers for requiring consent, and what does it mean for that consent to be meaningful, which is very much a part of our recommendations? Granular consent and, in particular, is the technology and the place to support patients providing consent at more granular than a yes/no, all in or all out level, and then some final conclusions.

With that, we'll reinforce what the scope of our recommendations are, and that is, they apply to the electronic exchange of patient identifiable health information among entities that are known to one another in order to meet stage one of meaningful use, so it's treatment and care coordination, which is right at the top of this diagram, public health reporting to the left, and quality reporting to the right. There's a lot of exchange that we know is occurring today, but is not covered by our recommendation. We really needed to be able to be focused in order to accomplish what we were able to accomplish over the summer, but we fully acknowledge that there are issues to be resolved involving exchange that is occurring today and that is important and that raises privacy and security implications. And that includes patient access to copies of their health information, research, and claims and payment processing. That's even acknowledging that those are left off the table does not necessarily cover the universe of all of the exchange issues that are yet to be resolved.

In addition to narrowing the scope of what we talked about, we also focused on some specific issues and questions that we were asked to address by the Office of the National Coordinator. Those include the use of intermediaries or third party service providers and identifiable health information exchange; the trust framework to allow exchange among providers for the purpose of treating patients. The ability of the patient to consent to participation in identifiable health information exchange at a general level, i.e. yes or no, and then how that should be implemented. The ability of the technology to support more granular consent, and then some additional recommendations that were part of a series of, again, and focusing on a series of questions, so this is almost like a miscellaneous category here, some additional recommendations with respect to stage one of meaningful use.

So now we get to our core tiger team recommendation involving Fair Information Practices, which is overarching. And that is that all entities involved in health information exchange, which includes providers, both at the individual and institutional or organizational level, and third party, what we call third party service providers or third party service organizations is the term we used in the letter, which would include a health information organization, which again is the noun form versus HIE, which is unclear whether it means just exchange or something in a noun, formal structure, so we use HIO, and those are third party service providers or third party service organizations and other intermediaries.

All of them should follow the full complement of Fair Information Practices commonly known as FIPs, when handling personally identifiable health information. In fact, in the letter, for each set of recommendations, we've mapped them to the applicable Fair Information Practice principle that they were intended to begin to address. And the formulation of the FIPs that we used, because there are a number of good ones out there in the health space, but the one we used comes from ONC's nationwide privacy and security framework for electronic exchange of individually identifiable health information, and this was adopted by the policy committee in the strategic framework document several months ago.

Now we also adopted a set of core values, which are really, again, the foundation for all of our recommendations here and, in particular, those involving individual consent. The first one is that the relationship between the patient and his or her healthcare provider is the foundation for trust in health information exchange, particularly with respect to protecting the confidentiality of personal health information. As key agents of trust for patients, providers are the ones who are ultimately responsible for maintaining the privacy and security of their patient's record.

We also must consider patient needs and expectations. Patients should not be surprised about or harmed by collections, uses, or disclosures of their information. Then ultimately to really be successful in these endeavors in the use of exchange to improve health and healthcare, we need to earn the trust of both consumers and physicians. These four core values really are the foundation of the recommendations that we are summarizing for you here today and that are in the letter. It is any time we had an issue that arose that we struggled to resolve, coming back to these core values inevitably helped us to get over the hump and to be able to move forward.

With that, we'll move on to our recommendations. With respect to the first two questions that ONC put on the table for us involving the use of intermediaries or third party service providers and the trust framework, these are recommendations that were previously presented to you, and they are, of course, in the letter. And they're in the appendix to the slide deck that you received. Since we don't have a lot of time on this call, we're not going to go over them in any detail, but we're happy to answer questions about them during the question and answer period. Again, these are recommendations that have been presented to you in the past, and so they should look familiar to you. But again, if you have questions that you want to raise, we can go over them during the question period.

With that, we'll get to the area of consent where we did do some modification to some recommendations that we presented to you previously based on comments that we had received, both from you all here in standards, as well as members of the policy committee.

With that, I'm going to turn it over to my co-cair, Paul Egerman.

Paul Egerman – eScription – CEO

I'm going to take you through recommendation number three. Deven is going to help me also with three, and then also number four on granular consent. This is consent and directed exchange. I think the standards committee understands full well what directed exchange means. It means going from provider A to provider B. What we said on directed exchange was that the existence of directed exchange does not require patient consent beyond what is required in current law or what has been customary practice.

The change from the last time that I gave you this information was we clarified, of course, current law because there are some state laws involving directed exchange, for example, with ordering certain tests, tests about HIV. There are some laws about what should and shouldn't happen in state laws. And so we wanted to clarify that those still apply. In customary practice, we also want to clarify just because we are saying that there's not a requirement for additional consent doesn't mean we want to change what practices may already exist, as many healthcare providers have already established practices that may require consent under some circumstances.

Then we also clarified these two bullets you see here that our recommendation really was not intended to change the patient/provider relationship by saying that it's not required. We didn't want to change whatever discussions are already underway in terms of information that may or may not be exchanged. We also clarified that basically what we're talking about here is comparable to what already exists when there's paper or fax exchanged. So when people do referrals, they sometimes do that by a fax or order test results or receive a radiology interpretation occasionally that will occur by fax, and so when those things occur, whatever those privacy considerations are should continue to occur.

Directed exchange is really, another way to think about directed exchange is really an exchange between providers. These are recommendations, I also want to emphasize, that relate to directed exchange between providers when it occurs for treatment. For treatment is really a critical understanding of this process. When the patient consents to the treatment, there's implied consent to exchanging the information.

Then the question is, when is there a trigger that does require consent? And this is what is written on this slide. This is considerably simplified from the previous description. We took into consideration the comments that we received from the standards committee, which received similar comments from the policy committee, that we wanted to make it clear relating to communications with interesting organizations like accountable care organizations, whether or not that was included, so if you look at what's on your slide or on your screen right now, it says when the decision to disclose or exchange the patient's identifiable health information from the provider's record, and then it's underlined, is not in the control of the provider or that provider's organized healthcare arrangement, OHCA. It's pronounced ō-ca, and I'm going to talk about that in a second.

When that occurs, patients should be able to exercise meaningful consent to their participation. What is this thing called the OHCA? Is it just some new acronym that we're pulling out of nowhere? This is actually something that is clearly identified within HIPAA and the concept of the OHCA, the Organized Healthcare Arrangement, is to try to describe these very interesting structures like the accountable care organization, the medical home. Some people have things they call community records. Even within a

community hospital, there are multiple providers involved. We're saying all of those entities are healthcare entities that are involved with treating patients, and our recommendation really isn't intended to apply to those entities. Our recommendation is intended to apply to entities that do not provide healthcare, that are not part of a healthcare arrangement, that are sort of exist in the world of the business associate agreement.

On this next slide, I have three examples. The first example is a centralized HIO model, and that's basically a model that's retained, identifiable, patient data, and that makes that information available to other parties, so that example, as that would require consent for a patient to participate because the control over who has access to the data is no longer under the control of the patient provider relationship. This other entity has that control. A second example is the federated HIO model, which exercises control by having control over who has access in effect to linkages to be able to access patient data.

The third example, it sounds like a mouthful when you read it. Information is aggregated outside the auspices of the provider or OHCA and commingled with information about the patient from other sources. What in the world does that mean? Well, I'll give you an example. That's like a company that's a vendor that's perhaps an e-prescription gateway, a company that helps transmit prescriptions from a physician to a retail pharmacy. If that vendor were in that process of transmitting the prescriptions were to maintain a medications profile on each patient, perhaps for multiple healthcare providers, that would be considered aggregating data from multiple sources on the patient. And so to participate in that, patient consent would be required because information would be made available to multiple sources.

Those are intended to be examples to make it clear that we're not talking about healthcare organizations when we're talking about this trigger for additional consent. Those are examples of what we are talking about. The concept of control, again, occurs by who can control who has access to the information.

On the next slide, we basically describe what happens with this consent, and what we say is, first, the patient must be provided with an opportunity to give meaningful consent before the provider releases control over the exchange decisions. The words meaningful consent are underlined, and we got meaningful use, and now we've got meaningful consent. Deven will review meaningful consent in a minute.

Basically you see the word ―before" in italics. Now if I was presenting to you in person, I would take my laser pointer, and I would likely circle all around the word ―before" and I'd be making all kinds of gestures and eye contact, all of which would be extremely effective, extremely effective, but the purpose of it is to emphasize the word ―before". You know, the idea here is you've got to get consent before the provider releases control over the exchange decision so that that would be the visual emphasis on the word before.

The second concept here is if the patient does not give consent to participate in a model that triggers consent, the provider should alternatively exchange information through directed exchange. Then there's a third concept here that's very important. There are some HIOs that offer multiple services. This is a concept that Wes helped considerably in developing. It says the provider may still contract with an HIO to facilitate direct exchange as long as the arrangement meets the requirements of recommendation one of this letter.

In the example I gave in the e-prescription gateway, if the e-prescription gateway maintains the medication profile on the patient, if the patient does not consent to allowing that to occur, you can still use that gateway to send and receive or to send prescription information to the retail pharmacy as long as the vendor doesn't accumulate that medications profile. Another example is a lot of the way some HIOs

frequently get started is with doing the tests and test results where they will facilitate transmitting an order to a laboratory. They will facilitate getting the test result returned back to the ordering provider. And, in the process, will accumulate a database of test results.

If the patient does not consent to accumulating the database of test results, that HIO can't accumulate that information, but they could still be used to send and receive the results. The provider, we're trying to make things as administratively simple as we could for the physician. The provider does not have to deal with two different HIOs to transmit information, if that's the vehicle they choose for their test results or two different e-prescription gateways, if that's the vehicle that they choose to do e-prescribing. Those are the concepts about consent that represented some very significant recommendations that we are making, and I made a comment about meaningful consent, and Deven will now explain that.

Deven McGraw – Center for Democracy & Technology – Director

Paul did a great job of getting into the details of our recommendations regarding when consent is triggered and when individuals ought to have the right to consent to whether their information is included in a particular arrangement. I think sometimes when you get into the details, it's easy to sort of understand them if you go back again to the core values that led us to that point, which is ultimately that patients trust their healthcare providers with respect to maintaining the confidentiality of their information.

In a structure that preserves the ability of the providers that they trust to make the decisions about when to disclose information, in directed exchange circumstances, it looks a lot like the circumstances that patients for the most part know and expect today. But in arrangements where in fact that control doesn't exist and the provider has given up that control, that's where it's not as consistent with patient's expectations, at least today. They may evolve in the future, but that's where we think they are today, and so we think that that's where ONC should promote a policy of giving patients consent in those circumstances.

The consent needs to be meaningful. What do we mean when we say meaningful? The next set of slides get to the elements of what we think are meaningful consent, and we relied very heavily on the Markle Foundation's common framework in developing these particular attributes of meaningful consent. An advanced knowledge and time to make the decision is a key one. This set of slides is pretty summary for you. If you want to get the details, of course you can look at the letter, which is where all of the details are. But we also, in the appendix, in slides 24 and 25, cut and pasted them out in the slides. But patients ought to be able to be making these decisions in advance and have time to make them.

It shouldn't be compelled or used for discriminatory purposes, and otherwise consent to participating in a certain HIO model should not be a condition of receiving necessary medical services. And we had a lot of discussion about this in the policy committee meeting, so people understood that what we were talking about is, again, where consent is triggered, which is when the provider no longer has control over decisions to disclose or exchange. And when you have that circumstance present, that's when a patient ought to be able to say I don't want my data to be part of this centralized HIO, for example. But that shouldn't mean then that the provider says, well, then you can't get care with me because that's not meaningful consent.

That's compelled consent, and that's very different from, and we're not talking about circumstances where you have provider record sharing, say, as part of an organized healthcare arrangement where, in essence, in order for a patient to say, well, no, I don't want my record to be, say, part of the partners healthcare system, well, then that really makes it impossible for a provider who is part of that system necessarily to provide that patient with good care. So there are distinctions there, and we made that very clear to the policy committee that the line that we drew is with respect to, again, an HIO where the

provider or providers organized healthcare arrangement doesn't have control over the disclosure decision anymore.

Full transparency and education, patients ought to understand what's being proposed for them in language that they understand and that is conspicuous. The consent needs to be commensurate with the circumstances, and what do we mean here? If you're talking about an arrangement that really deviates significantly from what patients reasonably expect, you need to provide a greater degree of education and time to make the decision or opportunities to discuss it with the provider. It needs to be consistent with reasonable patient expectations for privacy, health, and safety. And lastly, it must be revocable.

What we said in the letter, we didn't say that the revocation needed to be prospective only. We left open the possibility that some organizations might make the consent revocation retrospective or backward looking, but either way, it has to be very clear to the patient what their rights are with respect to revocation and how they apply, whether it's only on a going forward basis or whether in fact there's a look back, that needs to be made very clear. Again, there are details in the appendix and, of course, details in the letter. But again, if you take these two recommendations together, whether consent is triggered, it needs to be meaningful. And, to be meaningful, it needs to meet each one of these provisions, which we think is critically important.

With respect to how it's implemented, and I'm thinking, Paul, am I handing off to you?

Paul Egerman – eScription – CEO

Yes. I do this one. We have some implementation guidance on consent. First of all, just as Deven has described the core concept of the patient provider relationship, which is where the trust is maintained and the confidentiality of the patient's information, we say, of course, as a result, the provider has the responsibility to educate and discuss with patients how their information is shared. That's where the responsibility rests. But then we also say, the federal government, as well as the regional extension centers and the HIOs should be helping, that they all have responsibilities to educate the public and provide resources to providers to provide as much assistance as we can to providers.

The third concept is in terms of administering this whole process. Those first two bullets are predominantly about education. But somebody has got to keep track of all of this. You've got to keep track of whether or not patients gave consent, and if they ever revoked it, and when they revoked it. And they say, well, providers are responsible for doing that also. But they may delegate that consent management administration function to another party such as an HIO because what we're trying to do here is, on the one hand say it's the provider's responsibility to manage and implement consent.

On the other hand, we're also trying to make it as administratively easy and give as much support as we can for the providers to do that, and that's particularly important when you see what Deven is going to present on the next slide.

Deven McGraw – Center for Democracy & Technology – Director

Here it is. This is something, again, that you all have seen before. We spent a lot of time talking about what rights the patient has with respect to participation in certain models of exchange, and so we raised the question of whether providers should have a choice about participating in exchange models. The simple answer is yes, but recall that this is with respect to policy that ONC should put forward and doesn't necessarily—we don't have the ability to control what, say, states might say about this. But we think that providers ought to have a choice.

Paul Egerman – eScription – CEO

The next recommendations relate to granular patient consent. What does that mean? Well, what we've been talking about consent so far is sort of like yes or no. Yes, the patient wants to participate. No, the patient does not want to participate.

Granular consent sort of says can the consumer, can the patient decide they want to participate, but not provide all of the data? Can they say I want to participate, but I don't want my entire medical record to be exchanged? I want these parts that are sensitive not to be included. Making this recommendation in the letter, we acknowledge that all medical information is sensitive information. However, in state laws and in society, certain aspects are considered to be slightly more sensitive than others or perhaps more than just slightly. More sensitive than others, so these are issues relating to things like substance abuse, sexually transmitted diseases, reproductive health, behavioral health and mental health and so on.

The issue about the patient's ability to provide granular consent is an area that we looked at. We held a hearing on June 29th, which described in detail in the letter. We reviewed the prior recommendations of NCVHS, and we have NCVHS participants in our tiger team, and also, as you can see in the third bullet here, we had the cochairs of the NCVHS confidentiality and privacy workgroup make a presentation to our tiger team, so we understood what they were currently reviewing and doing, and apparently they will be producing a new letter in the coming month of September. And we got sort of an advanced look as to what will be in that letter.

Based on all that information, we came to the following conclusions that with regard to consumer or patient choice to make granular consent, to consent to sections of the record, with regard to that issue, we said the technology is promising, and people have done some really excellent work. We think it's still in an early stage of development and adoption. Basically we're saying it's not yet ready for ONC, for example, in stage two to be writing certification criteria around it.

We're saying further experience and stimulation of innovation is needed, and this should be a priority area that ONC should be emphasizing the ability for patients to have greater flexibility. But we also say it's really important, you see it on this slide, that ONC find evidence, perhaps through operational pilots, for successful models and not simply rely on theoretical possibilities. And we also say, in the interim, patient education is paramount, and realistic expectations about privacy need to be established.

Deven McGraw – Center for Democracy & Technology – Director

The last question is really a set of additional recommendations. It's actually a series of questions regarding exchange of data for treatment, quality reporting, and public health reporting dealing with things like degree of identifiability of data, whether one patient's information can be exchanged for the purpose of treating another person. All of these recommendations were previously presented to you, so we're not going to spend time on them today, but they are included in your appendix and, of course, they're in the letter, and we'd be happy to take any questions about them if you've got them.

Last, to conclude our presentation here, I want to say again that these recommendations were targeted to address a particular set of questions raised by ONC and were limited to, again, stage one of meaningful use. They are not the definitive or final word on privacy and security on health IT and health information exchange. More work is absolutely necessary, and only a systemic and comprehensive approach to these issues is going to be able to achieve the public confidence that we're going to need in order to move this forward in a trustworthy manner.

Among the issues that need further work, exchange beyond stage one seems obvious, provider credentialing assurance levels, individual access to health information, transparency of health information exchange, security safeguards, and policies around deidentified data. I suspect that some of you would

add different issues to this list. We know we have more work to do in the future, but we think we've laid a good foundation with this initial set of recommendations that will hopefully help us to reach some conclusions about some of these other issues more easily. Of course, whether that's true or not, we shall see.

We've given ourselves a little bit of a break after a pretty intense summer, and we're going to be sitting down with ONC, Joy Pritts in particular, to map out what the right next steps are for the fall and beyond. But we thank you very much for the opportunity to share this with you, and now we'll open it up to any questions you have.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I just want to make one friendly clarification, which is that our previous, before you got to the granular consent recommendations, our previous recommendations are not necessarily all or nothing. If a provider is in control of what information is being exchanged, the provider, just as they do today, has the discretion to fulfill … the patient's wishes.

Deven McGraw – Center for Democracy & Technology – Director
Yes.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So I don't think it's right to say all the previous recommendations are sort of all of nothing. Are you sharing all your data or not? They are purposefully structured that way because the provider and the patient can exercise some control about what to share and with whom. And it's a distinct issue from what technology is used.

Paul Egerman – eScription – CEO
Carol, it's a good comment. Yes, because you're exactly right, and the issue is that the provider still has the control over what's exchanged, and the technology that we were really looking at was the technology for patients to actually get access to what is being exchanged and to alter it, but an excellent point.

Jonathan Perlin – Hospital Corporation of America – CMO & President
If I could just run us through an operational example, I mean, I like your work very, very much. Kevin Hutchinson, you'll probably want to listen to this and comment. I imagine e-prescribing is checking a patient's eligibility, and that is a nonpersistent transaction. There is no, there's data set transiently, but there's nothing deposited in a repository. That results in a formulary being activated and a medication is checked against the formulary. There's really nothing persistent there. But then a drug/drug interaction check for safety should take place. Of course, that would imply that the e-prescribing entity, the HIO, had a list of previous transactions for which a drug/drug interaction check could be done. Oh, by the way, medication reconciliation, which is part of meaningful use, also is empowered by such a thing. However, again, that now crosses the line into persistence.

Deven McGraw – Center for Democracy & Technology – Director
Right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Routing is transient and, therefore, it goes from provider to pharmacy. And assuming that's part of the patient is going to have to go to a pharmacy or a mail order pharmacy to get the medication filled, but it's transient. And then finally, refill. Refill initiated at the pharmacy back to the provider is transient. So the challenge here is if I look at e-prescribing networks in America today, there is the notion of achieving consent for the transaction before the transaction happens. But there is indeed, I participate in the

transaction but don't participation in the maintenance of history for drug safety checks. I mean, Kevin, from your perspective, does such a capability exist?

Kevin Hutchinson – Prematics, Inc. – CEO
I'm glad you brought it up because I was chomping at the bit. You guys are on a topic that's very near and dear to my heart, obviously. And I notice and appreciate the differences between an HIO model and a direct exchange model. And in the industry today, the way the medication history works is not really through an HIO model because it's not aggregated in a single spot and then delivered. And I'm wondering if it's the direct exchange rules that apply or the HIO models that apply because what transpires is a search for a patient's medication history of which the sources, be it retail pharmacies or PMBs or health plans, then respond with a positive match and exchange that information upon the request of that transaction. It's not stored in a separate place where it is then delivered. It is aggregated at the source level. So is that a direct exchange from a provider to the pharmacist to a physician, or is that considered an HIO model where it's aggregated?

Paul Egerman – eScription – CEO
It's hard for me to respond because it's always hard to respond. It's sort of like a theoretical model. To do my best to respond to the model that John Halamka, I think it was John who made the comment about the medications profile. I would say the way a lot of EHR systems works is the medications profile is actually maintained within the provider's own medical record and through a medications reconciliation process, hopefully that is close to being up to date, and so that's how you do a lot of drug/drug interaction work.

Where you get into the trigger for consent is if the e-prescription gateway is the place where the medications profile is being maintained from multiple providers. That's where you would get to a consent environment and, in talking to at least one of these, I'm under the impression you can separate out what John called the transport of process from the process of actually storing and retaining the patient's information, that those can be separated. In response to the other question is if you can obtain the information from other sources through directed exchange and store it in your own electronic health record though, then that doesn't trigger consent.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think that we have a couple issues here. One, for all intents and purposes, the pharmacy is a provider. The pharmacy is responding to a request from another provider, the physician, that was mediated by the e-prescribing network. The only issue here is whether a provider is in control of releasing information. In fact, the pharmacy is.

Deven McGraw – Center for Democracy & Technology – Director
Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So as long as the technological model follows what Kevin described, which is to say there is no repository being built up by anyone who is not a provider to deal with the transaction, it's a matter of the relationship between the patient and the pharmacy with regards to what information they'll release. And I believe the level of consent they get wouldn't necessarily pass Deven's sniff test, but it's what….

I wonder if I might comment on another part of the discussion.

Deven McGraw – Center for Democracy & Technology – Director
Wes, before you do that, can I just add maybe one or two sentences to the preceding discussing, which is to say that based on the control remaining with the record holder in the circumstance that Kevin described, I would agree. I think it's a direct exchange circumstance for which we said we don't see a need for additional patient consent beyond what would already be required in law.

Having said that, there's a whole transparency piece that we really haven't gotten to. I'm not sure the patients fully sort of understand how those transactions take place today, and we'd be greatly benefited if they did. But we need to get to that in future discussions, so that's all I have to say about that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I just wanted to add another comment, Wes, before you change the subject.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Sure.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I know we had a lot of discussion about this, but the issues, the keyword is control rather than the distinction about whether the data is in place A or in place B. So whether it's centralized or whether it's distributed, the question is, does that network manage control of access to the information regardless of where the information lives? If you simply distribute the information, it doesn't relieve you of the requirement that the information is under control.

So directed exchange implies a certain amount of control between the sender and the receiver. If that's missing, then it doesn't qualify. I think that's consistent with, Deven, what you just said. It's not about where the information lives. It's about what controls exist to guarantee that the access is appropriate.

Kevin Hutchinson – Prematics, Inc. – CEO
Before, Wes, you change the subject, let me ask one other expanding question on this because I would hate to see us go backwards in the direction we've been able to allow medication history availability to help improve patient care for physicians and their patients. PBMs are a major source of the medication history today. I think we all recognize that the PBM is not a provider of care, whereas a pharmacy is and a physician is. Most of the major retail chains are providing that data. And where that data is not available, the PBM source is still the gaps for independent pharmacies and where other information is no available. They also have their own mail order pharmacies as well. But are we going to have different consent, whether that source is coming from PBM files or health plan files versus coming from pharmacy files? This could start getting interesting from an implementation standpoint if that is true.

Deven McGraw – Center for Democracy & Technology – Director
Kevin, we just haven't addressed the question yet, I don't think, in part because of the scope that we focused on exchange of data among providers on the consent piece and then also limited it … PBM play an important role in the payments aspect. I'm sorry. Can people hear me? I'm getting an echo.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, someone has unmuted their phone while they have the speaker on. Now it's gone.

Deven McGraw – Center for Democracy & Technology – Director

I just don't think that, I mean, I think it's a really good question, but I don't think we've covered it yet. Keep in mind that we dealt with the issue of consent among providers for treatment purposes, and a PBM isn't a provider, as you mentioned. So we don't have an answer to your question yet.

Kevin Hutchinson – Prematics, Inc. – CEO
Okay.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
But a PBM is a HIPAA covered entity.

Deven McGraw – Center for Democracy & Technology – Director
It's a business associate.

Kevin Hutchinson – Prematics, Inc. – CEO
No, they're a covered entity versus a business associate.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, they are. You're right.

Deven McGraw – Center for Democracy & Technology – Director
A PBM?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, it's an insurance company.

Paul Egerman – eScription – CEO
Yes, a PBM is an insurance company.

Deven McGraw – Center for Democracy & Technology – Director
Right.

Paul Egerman – eScription – CEO
Then probably you don't need consent. Yes, they're a covered entity.

Deven McGraw – Center for Democracy & Technology – Director
…does not deal with insurance company issues, so what the recommendation covers versus what's in the law, I mean, yes, you don't need consent today to share data fore payment purposes.

Paul Egerman – eScription – CEO
Yes. It's important to keep in mind the recommendations said for treatment, and so we really aren't dealing with payment issues or research issues. We really were trying to be very focused.

Kevin Hutchinson – Prematics, Inc. – CEO
Yes, this is for treatment….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
…treatment, right?

Paul Egerman – eScription – CEO
Yes, we're talking about drug/drug interactions. That's treatment.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Sure. What it boils down to is we haven't addressed the issues where the source is not a provider yet.

Cris Ross – LabHub – CIO
I think there's a case here in pharmacy that extends elsewhere. For example, in the case of there's a lot of independent pharmacies who do not maintain their own e-prescribing system, but use a vendor to do it on behalf of multiple operations. And, in that instance, those pharmacies have asked their vendor to maintain transactions on their behalf. It may very well be that in some sense that vendor is acting as an organized healthcare arrangement for that selection of providers, selection of pharmacies.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I want to bring up the discussion of organized healthcare arrangement because I'm not at all sure about that. I wonder if Adam is on the call today.

Cris Ross – LabHub – CIO
Wes, I think that is. Let me just finish the thought because maybe we agree on this, or I don't know. We may agree on what questions to raise. The pharmacy one is fairly well understood, so we could explore it, but I wonder about the case in which vendors are acting as maintaining records on a persistent basis just to maintain the other things that an organization needs to do around auditability and other kinds of things.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
If I use a vendor for my patient record that's remotely hosted, and they do some interfaces for me, they're a business associate, and they do what I tell them to do in that regard, which would be the same with your pharmacy system vendor, I think.

Cris Ross – LabHub – CIO
Right.

Paul Egerman – eScription – CEO
Yes. Excellent answer, Wes. That's what I was going to say in a lot more words. You said it better.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, but I'd like to look, as an organized healthcare arrangement. Adam is the one who brought it to our attention. As I understand it, it is a group of providers doing business together, and it's recognized that that group of providers can work as a single entity under HIPAA. They don't have to have the same level of business associate agreements and so forth because they're organized to provide healthcare as a single entity. And somebody will correct me if I've got that wrong, but if I don't, then I want to clarify that not all directed exchange comes within an organized healthcare arrangement. That is ….

Paul Egerman – eScription – CEO
That's correct.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
If a physician refers somebody to a radiology practice, sends along some information about what the case is, and then gets a referral, a constant letter back, those don't have to be operating as an organized healthcare arrangement for that exchange to be directed exchange.

Paul Egerman – eScription – CEO

That's correct. That's a good clarification. That's correct.

Joy Pritts – ONC – Chief Privacy Officer
Wes, an organized healthcare arrangement requires a little bit more than you described it as. It's essentially correct, but I don't think that we need to go that far into the grass, into the weeds on this call.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. That's fine. I mainly wanted to clarify that it's not any case of people, of agencies working together, and that it was….

Joy Pritts – ONC – Chief Privacy Officer
That's absolutely correct, and it does require that they hold themselves out to the public and being engaged in the pubic in a joint arrangement for one thing.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So the physicians all wear logos on their lab coats or something, T-shirts with their name on them. The other comment I wanted to make related to the recommendations with regards to, and I'm just going back in the presentation. It was, I think, number four. Yes, four, ability for more granular consent. We heard in testimony that the mechanics are available through the work that's been done under the NHIN Connect project for implementing more granular consent, and we heard some relatively simple examples of maintaining that. I think, to clarify, this statement, the reason we need more experience, despite the fact that it's being used in certain limited circumstances, is that those circumstances are so limited as to not make it clear that there's enough available in the standards and in how the standards are implemented to make it practical on a larger scale.

Linda Fischetti – VHA – Chief Health Informatics Officer
Wes, from the provider perspective, I agree with you fully. It was in April 2008 when OASIS HL-7 hit CIHE, and then VHA was a strong leader in that, along with Sun Microsystems, Red Hat. We're able to demonstrate the granular consent methodology as part of a HITSP project. While we were one of the leaders of doing that demonstration, it has been frustrating how long it's taken to actually take a concept that we were championing and bring it into our operational systems.

The one thing I was going to speak to was the second bullet on recommendation four. There is absolutely a need for continuing innovation dollars to be able to address this issue. This is one of the most important things we want to deliver for our veterans. And even though we've been working on it for quite a while, we still don't have it live right now.

Deven McGraw – Center for Democracy & Technology – Director
Yes. Thanks.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
One of the things I think that came out of the testimony from VHA was that there's an ongoing tradeoff between how granular the consent is and how much assistance the patient needs understanding the consent they're giving to the point where we even started talking about an entirely new job category, which was the patient privacy advisor or something like that. That's part of the difference between what's technically possible and what's practical in a real world.

Paul Egerman – eScription – CEO
Good comments.

Kevin Hutchinson – Prematics, Inc. – CEO
I have one other question going back to the concept of the—just as a sample. It applies to anything, but going back to the prescription comment. A lot of these medications—my question is going to be centered around access about where we define access. Is access when the physician is in the act of viewing the information, or is access when the system is in the exchange, process of doing the exchange?

The reason why I ask that question, it's really important is if you've been implemented across the country today, a lot of the medication history and eligibility transactions, although I know we're not talking about claims things here, happens at night simply for balance of system performance and network performance and other things like that where patients that are scheduled the following day, transactions at 2:00 a.m. may go out, pull eligibility, pull down medication history. It's not accessible to anyone at that point until they put in that they have the consent, that they have patient consent, and then they access it.

So would these new rules require that the actual transaction not occur until there is – of course, there could be forms that would be signed or some other step above HIPAA where today as long as the physician has the rights to gain access to the patient's medical information for the treatment of care, then that's then used for consent purposes up to this point. But assuming it's going to go something above and beyond that, I noticed I can count the laser point would have been circled around —before" multiple times if it had been presented in person. So in that scenario, are we saying that we are no longer going to allow the systems to exchange information in the wee hours of the morning versus access to it?

Paul Egerman – eScription – CEO
While we were talking, I moved the slides back to the trigger, and the trigger says, when the decision to disclose or exchange, so disclose is access. If the decision as to who gets to access the data or exchange the data is outside the control of a provider, then consent is triggered. Whether or not it occurs at 3:00 in the morning or 3:00 in the afternoon is not relevant according to when we made these recommendations. We are simply saying that that is the trigger. That the key issue is, who has this control? Is it a provider, or is in an HIO?

Kevin Hutchinson – Prematics, Inc. – CEO
Okay.

Deven McGraw – Center for Democracy & Technology – Director
Yes. Like we were talking earlier, Kevin, I'm not sure that the circumstances that you're describing actually qualify as a trigger. Paul says disclose is access. I'm not sure I agree with that, but I'm not sure that the difference is all that relevant. If you think about sort of the pharmacy being a provider, and deciding to disclose the data versus sending it to a repository where that decision is not in the provider's control anymore, I mean, that's the distinction we were trying to draw here. I agree with Paul. If you don't have a control release, regardless of when the decision to disclose happens, I don't think is relevant. And I don't think we were talking about a per transaction consent arrangement.

Paul Egerman – eScription – CEO
That's right. Yes.

Deven McGraw – Center for Democracy & Technology – Director
If you even have a trigger to begin with, which I'm not sure you do….

Kevin Hutchinson – Prematics, Inc. – CEO

You could provide the same scenario to whether it's prescriptions or labs or medical summaries or referrals. There are a number of different types of transactions you could apply the same questions to, so I'm glad we're having this conversation.

Deven McGraw – Center for Democracy & Technology – Director
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Obviously a very robust discussion, and I think everyone participating in this discussion as a provider was trying to envision the complexity, and I resonated with Kevin Hutchinson's point that there's certain entities that seem to be somewhere between fish or fowl. If I were to receive a patient, I would want to be sure that I had the data to reconcile that didn't introduce a drug error where current processes would allow that, and appreciate the thoughtful consideration that the tiger team, Paul, and Deven are giving to those real world complexities where we want to make sure that the trust fabric really creates the context for the seamless movement of information, but that the seamless movement of information is realized in that process. And I realize it is extraordinarily complex dialog and one that's getting more complex with the new forums that really define the traditional categorizations. So we may need really additional work in this sort of standard classification of the entities that are participants in these complex relationships.

We're going to move to a more sort of technical level in our next sets of discussions about vocabulary and S&I framework. Let me ask my co-chair, John Halamka, to introduce the next discussion.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much. Thanks so much, Paul and Deven. I think this is a very rich framework, and I look forward to implementing in our local HIE. The proof will be in the doing. As I talked about it at the beginning of the meeting, the S&I framework is going to provide a foundation for us as an HIT Standards Committee to insure robust processes and tools are in place for standards harmonization, creation of artifacts, testing plans, all the kinds of getting new standards and new transactions done in the real world.

There were a series of RFPs that were issued, and Doug will tell us about those RFPs in process and those that have already been awarded, and give us some background as to some next steps. My view, the HIT Standards Committee will play a very important role in providing oversight, coordination, and prioritization advice on the standards interoperability framework to Doug and to ONC. Doug, take it away.

Doug Fridsma – ONC
What I want to do is just sort of set the context. Some of these slides we've seen before, but I want to make sure that we frame the kinds of discussions that we have, and then I will provide that update about some of the contracting issues and kind of where we are at this point. So I guess the first thing is that part of the motivation for this work is that there's been a lot of previous standard efforts. John is very familiar with some of the ones that have come out of this office as well.

But I think it's important to recognize that standards are not things that we necessarily impose, but they are best when they are adopted. And so to improve the adoption, we have to solve real problems, not abstract ones, and we need to be able to engage the community so that they have a sense of ownership. I think one of the initiatives that we have here with the NHIN Direct project is really an example of how perhaps getting together people who want to try to solve real problems and engaging the community does help us drive forward the adoption and use of standards.

Standards also should be harmonized and commissioned based on clearly articulated priorities. And so we need to have some way to coordinate and prioritize the work that we have. Certainly in the past there

have been those kinds of mechanisms in place, and we right now have the HIT Policy Committee and Standards Committee to help guide and provide recommendations for the kind of work that the government should be pursuing.

We need to make sure that we have tools that will accelerate the adoption, and that includes … vocabulary. I know that Jamie Ferguson is working on a series of hearings that will happen later this week to address the issue of vocabularies and how best to do that. And it's also important that we have very easy to use implementation guides so that we have tools that can help with adoption, and that implementation specifications are easy to use, easy to understand, and difficult to misinterpret in terms of how they go forward.

We have to make sure that we keep things simple. If we're going to be solving real problems, we need to make sure we don't try to boil the ocean, but solve real, focused problems, but be able to use that as a beginning point that then we can build out, as we move forward. And that perfection is the enemy of good because we need to iterate and improve and have a mechanism that allows us to have that sort of work.

As we look at some of the work that's been done in the past, and we look at the tasks that are on our plate going forward, one of the things I think that's important is that as we have continued emphasis on standardization, we need to get to the point where we have increasingly computational implementation specifications. What I mean by that is that we need to be able to have a mechanism that we have implementation specifications that can be manipulated with tools. And so we have data specifications or vocabulary resources that are stored in repositories that then can be used by people interested in information exchange rather than having a set of descriptions perhaps that would be difficult to harmonize or difficult to browse.

It's important for meaningful use that we link use cases and standards from the inception, from the problem that we're trying to solve, all the way through to certification. And so we need to be able to make sure that we've got implementation specifications and standards that can be tested for certification, and that means involving NIST and others early in the process. And it's critical that whatever process we choose that there's the integration of multiple SDOs with different expertise across the process. And that includes transportation packages, vocabularies, and value sets, as well as sort of the integration of security into a more comprehensive framework.

What I hope people will understand is that the standards interoperability framework is really the mechanism by which ONC will manage implementation specifications, and hopefully assist in the harmonization of existing IT standards to promote interoperability and meaningful use. So it's important to understand that the S&I framework is not intended to develop new standards, although we will have to work very closely with standards development organizations when we identify … but we want to be able to work with organizations throughout the healthcare domain and help, in some sense, come up with a shared understanding of what the requirements are for interoperability. And so to document them in these computational ways so that we can use UML and the NIEM process to help us better support the implementation specifications.

Next, we hope that this will give us a bunch of benefits. I hope will help us manage the lifecycle because standards are not something that you simply sort of declare or implementation specifications are not the sort of thing you simply declare. You need to actually be able to go and refine them as new technology comes out or as new kinds of exchanges are necessary.

There's also some hope that we will be able to reuse the standards that we have across multiple use cases. We don't always start with a blank sheet of paper, but in fact are able to reuse data element

specifications that have been developed for one use case in a use case for, say, another purpose. And we need to develop some sort of semantic discipline so that the work products are developed in a way that insure the maximum computability and traceability throughout the lifecycle.

It could be that early on we have an understanding that we have the ability to exchange, but may not have the degree of semantics, computability if you will, or standardization. And so, in terms of managing that lifecycle, we need to be able to make sure we have the ability to go from things that are perhaps less specified to things that are more specified, that sort of graceful degradation, although I think Wes had a different term that he used for that. But we need to be able to have work products that can migrate to that lifecycle.

Ultimately, human consensus is the first step to achieving sort of computer consensus or computer interoperability, and so we need to have that sort of process in place. And so one of the things that we've been working on for the last couple of months is trying to come up with a framework that will help to support this. And there has been some delays in getting the contracting process out there and getting all of our contracts awarded. But, at this point, we are within just a couple of weeks of having all of our contracts out there. And so I think it's time for us to be able to sort of identify who are the folks that are going to be doing this work, and how this is intended to help support the work of implementation specification and standards.

This is a description or a picture of sort of the standards and interoperability framework. If you take a look, the use case development and functional requirements contract is in the final stages of review at this point. We hope to be able to make an announcement within the next week or so. I was even exchanging information this morning around that particular award. The harmonization of core concepts, which is really sort of a NIEM framework and the implementation specifications, has been awarded to Deloitte. If you think about the use case development as being sort of outwardly looking and trying to develop a community of users that would then come to the table with functional requirements and the like for a particular problem to solve, the Deloitte team will be more inwardly looking in the sense that they will assist those teams in trying to translate those use cases and functional requirements into a standardized way of looking at things within this NIEM framework. From that, they will hopefully develop implementation specifications based on the IEPDs that come out of NIEM and augmented by some of the needs that we have to describe services and not just data elements.

There's another group then that has gotten two of the contracts, the first being reference implementation, and the second being pilot demonstration projects. Those two contracts went to Lockheed Martin. The goal of the reference implementation is really to make sure that we got our implementation specifications right. They will serve in the role of testing the implementation specifications and making sure that we aren't missing anything, that the implementation specifications can actually…. And then helping us with pilots that will both test those implementation specifications in the real world, as well as looking at new ones that may need to go out there.

There's another group, certification and testing. We've sort of lumped those together, but those actually represent two different contracts. There is a certification that is currently under review, and there is a series of testing tools that was awarded to Stanley. Stanley received the testing contract, as well as the tools and services to help support the interoperability framework. They also currently support some of the operational features and operational functions of the NHIN as well.

There's one that we are in the process of rewriting the RFP, and that's the standards development contract. The goal there was to provide some focused work when we had identified a particular standard that needed to be brought through to an SDO or the creation of value sets or other things that might help

us with standards development. That particular contract, we've elected to recompete. And so there will be a little bit of a delay in getting that one out there, but we hope that we can do that expeditiously. We're certain that there's a lot of work that still needs to be done to try to bring all these pieces together.

With each of these awards, it's been critical for the participants that we do not start with a blank sheet of paper and that we leverage all of the work that's been done in the past. And so, for example, when it comes to the harmonization and implementation specification work, we have to leverage the work that's been done in the past with HISTP, particularly as it relates to meaningful use. The work that's going on with the reference implementation needs to leverage some of the work that's going on with Connect and FHA. Certainly, the certification and testing team needs to extend the work that we have with the NIST conformance tools and make sure that we can put those together in the sets of testing environments that will allow people to use the reference implementation, make sure that that's working for them, and string together some of the conformance tests into really business scenarios where you send things and get acknowledgement back and then resend then if there needs to be updates or the like.

And so throughout this, we've got a whole series of contracts that are currently getting started. Most of these have been awarded really within the last three weeks. And we have plans that in the middle of September, we'll have everybody come together and sort of launch how we expect people to work together to make this happen.

I think the thing that we're trying to achieve in this is, you know, there's this tradeoff that we have between command and control, sort of top down development of standards and implementation specification, or letting lots and lots of people sort of do whatever they want in hopes that from there there's 1,000 flowers that bloom, and we can just pick the prettiest ones that are there. I think what we're really trying to do is get this notion of focused collaboration. I think a good example of where we're going with this is that we have had tremendous engagement in the community around the NHIN Direct project, but if we pair that in with the interoperability framework, we hope that that will help us from the bottom up develop the kinds of standards and implementation specifications we have, but within a larger framework that will help coordinate that, and that's going to require for us to develop prioritization, some transparency, engagement of the community, and really trying to iterate rapidly, as we develop the standards and implementation specifications.

In large part, what we're trying to achieve with this is not to have the standards and interoperability framework essentially develop all of the implementation specifications or standards in a vacuum, but actually to have that serve as a platform that will support the work of the larger community and provide a way for collaboration to occur across a broad set of stakeholders. And so, if we think about that, the NHIN Direct project was developed using some rapid iteration developing working implementations and lots of feedback from the real world. We need to leverage that kind of work and make sure that that fits into sort of the larger framework, that as we have multiple kinds of uses cases out there and multiple groups that are working on that kind of engagement, that we have the ability to get all of those folks to collaborate together in a focused way around the priorities that we have and around the work that we have going forward.

In large part, we need to be able to leverage the HIT community. We need to be able to take professional organizations, government agencies, standards development organizations as well, and make sure that all that work that's going on with regard to developing specific solutions to use cases all comes down to sort of a harmonized set of standards and implementable specifications that can be integrated across the work that we have.

There's another way that we can sort of look at this as well when we think about the very specific kinds of standards that need to be constructed. So we need to think about transportation standards and certainly the NHIN Direct project has looked at the kinds of communication protocols between systems, but we have to make sure that we develop the content exchange standards, certainly those that have been adopted for clinical summaries, prescriptions, and electronic documents. We need to make sure that we have standardized nomenclature, code sets, and value sets that will help support the vocabularies. Certainly we hope to get some additional feedback later this week from the vocabulary hearings that are going on. And throughout this, we need to make sure that we have privacy and security that all fit together to support the implementation specifications that we have.

It's going to be a challenge, clearly, as we go forward. And I think we have to, as we think about this, develop some strategies and get feedback from the people that are on the HIT Standards Committee and in the various workgroups. So we've got a lot of different health information exchange standards, specifications, and different approaches to implementation, and we hope that we can begin to sort of solve real problems around meaningful use and make sure that we identify from that those exchange requirements that exist, identify any gaps, implications, or overlap, and work to develop kind of a core set of standards and specifications that will help support meaningful use.

There are some issues around usability of existing HIT standards and specifications, and I've been very clear with the groups, as they started to think about their approaches, the various contractors, is that complexity will be our enemy. And that to whatever degree we can simplify the work that we have and have very clear implementation specifications, perhaps even implementation specifications that can feed into software development tools that are out there, I think we will have much better successes in getting the standards adopted and used in ways that will eliminate or reduce, I should say, maybe not eliminate, but reduce the ambiguity that we have with some of the specifications.

We know already many of the things that we will require for healthcare exceed the existing NIEM processes, tools, and artifacts. And we've been working very closely in extending the NIEM processes to include not only specifications of the data, but also to include specifications around the services that need to be described and the behavioral aspects of standards as well. And so we're currently working on taking the IEPV, and extending that in ways that include some of those kinds of behavioral and service descriptions as well.

It's going to be clear that we have to harmonize and manage vocabularies and value sets and get to that level of specificity, and so leveraging existing vocabulary repositories and collaborating with standards development organizations and those folks that have expertise in managing vocabularies and value sets will be critical. And we have to make sure that we have the ability to support sort of the balance and effective participation of the HIT stakeholders. And so there needs to be engagement at all levels, I think, as we go forward so that we have the kind of expertise that we need to support this work.

When we think about coordination, there are probably at least three levels in which that coordination has to occur. At a strategic level, we have to make sure that we're aligned towards achieving specific goals, and I think certainly within the setting of meaningful use, we've got some clear goals there. But we also have federal partners, and we have other groups that may or may not be specifically – whose purview may be larger than just meaningful use, and we need to make sure that as some of those folks get ahead of the curve and are starting to work on things that are more forward thinking, that we think strategically about how all of us can converge and establish those goals.

We have some operational coordination that's needed so that we can effectively prioritize and manage our work so that although we hope to make available as many tools and resources that people can be

self-sufficient with, clearly we probably have more work that needs to be done than resources to support that. And so effectively prioritizing and managing that work and getting broad input on that, I think, is going to be critical. We also have sort of technical issues. We have to make choices in terms of how we will represent information and how we will manage and version and coordinate around the models and standards that are sort of being promulgated, and so that's also going to be an area of … that will be necessary.

What we really want to be able to do is have sort of this top down approach that helps us with goals and kind of recognizes things that are accepted as implementation specifications. But we want to make sure that we drive this bottom up and that we establish collaboration and involvement of the standards community and the various HIT stakeholders in the process. And so in some sense, the S&I framework really is a platform for collaboration around standards, but focused on helping us solve real problems in this bottom up way. And so although the contractors will help us establish some of that infrastructure and will help us manage some of that operations, effective—if it's to be effective, that whole standards and interoperability framework needs to have coordination with the community in participation so that we do the right thing.

If the S&I framework is to be successful, it needs to have sort of sustainable, transparent, and repeatable sets of operations that really echo what we've talked about … principles. We need to establish problem oriented approaches to identifying, prioritizing, and executing activity. We have to develop and adopt processes that insure collaboration and transparency. We need to identify avenues, which will facilitate stakeholder engagement, and provide infrastructure that will get us to the goal with some rapid results.

So I want to sort of end with this last slide, which is, this is really, I think, what we're trying to achieve in a standards and interoperability formwork. Trying to figure out how we can make sure that government, as a platform, can support the work of organizations and stakeholders like NHIN Direct to come up with problems that they want to solve, and that we can provide a framework that helps us collaborate around prioritization, transparency, engagement, and rapid results so that we can reuse the standards that are out there that we can maintain consistency across the standards and implementation specifications that are developed, and that we can make sure that they fit into the needs that we have within the meaningful use work to make sure that we can drive this towards certification criteria as well.

With that, John, I'm going to sort of turn it back over to you, and see if there are questions or other comments about what it is that we're trying to do.

John Halamka – Harvard Medical School – Chief Information Officer
I think all of us are very interested in providing coordination, oversight, and prioritization to help you in this activity. And it would seem that one of our collective risks is that the application of the NIEM framework in the past has been the Department of Homeland Security, Department of Justice, where it may have been that there were less existent standards, less existent interfaces, maybe there was a greater sense of urgency. It will be fascinating to see how you can take a framework that's worked successfully in government, which maybe has slightly different environments, slightly different complexity, slightly different data models, and graft it into healthcare. So I think all your principles are very good, but just want to raise that as a risk, and any comments you have on that risk.

Doug Fridsma – ONC
I think, John, you raise an important risk that's there. I think that indeed even in our experience that we've had with some of the early work in looking at, say, C32 and the like, we recognize that there is perhaps more complexity in some of the problems that we're trying to solve within healthcare than there are in some of the other kinds of data exchanges that are out there. I think we'll have to be vigilant about

that. I think part of what I've tried to emphasize as well is that the process that NIEM goes through to sort of come up with the data specification is not actually that dissimilar to the kinds of processes that we have within other standards organizations, certainly those that have been used within CDISC, some of the work that's gone on with HL-7, and other organizations like NCI.

Each of them have sort of a slightly nuance difference, and some of them have different approaches to tackling those problems. But I think there is consistency that there are certain things that you have to do. And I'm hopeful that the NIEM process will give us that framework to do that and allow us to take the best from all of the different organizations and all of the different processes, and incorporate them into a collaborative framework.

John Halamka – Harvard Medical School – Chief Information Officer
Let me open it up. I'm sure there are many questions.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I like the overall approach and the collaborative nature. I guess where I have some confusion or I don't have a clear picture, maybe is a better way to say it, is how, you know, the interoperability framework interacts sort of with the formal processes in the other standards development organizations. In particular, I'm thinking, if you need a new standard, to what extent you may in fact be able to rapidly make a new prototype or propose a new standard. Does that need to go to ballot somewhere? Can you use the existing standards organizations balloting process, or does ONC actually envision sort of becoming an über standards development organization where there would be a formal way of balloting those things within ONC itself? I like the approach, but I can't see the details of how those interactions are going to occur or how you envision that.

Doug Fridsma – ONC
I think the goal here is to help coordinate across all of the different standards development organizations. I don't see this as being an über standards organization in which there might be balloting or that this is going to replace the work of the SDOs. I think one of the things that is clear, and we've seen this in many of the requirements that we have, both for meaningful use, as well as with some of the activities with healthcare reform, is oftentimes we are faced with … tight timeframes to come up with a recommended set of standards or implementation specifications or the like.

It is useful, I think, to be able to have organizations that can come up with a potential standard or a potential way of exchanging information very similar to NHIN Direct, and then once that sort of – all those pieces have come together, what's going to be the transfer? What's going to be the content? What's going to be the value sets and vocabularies and terminologies? That then you've got that package, and you can then work with the SDOs to make sure that those things can be balloted in an appropriate way. That's, I think, what the vision would be.

We are cognizant of the OMB circular A1-19, which really puts into the framework that the government doesn't have the job of creating standards, but rather, identifying perhaps the needs for standards and then working with the SDOs to make sure that we've got that. Much of this framework is an effort to create a common way of representing what those requirements might be, what the problems are that we're trying to solve. Creating those implementation specifications that will be based around existing and perhaps standards that need yet to be created, and then working with the SDOs to make sure that they get balloted appropriately.

John Halamka – Harvard Medical School – Chief Information Officer
Other questions?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. A couple of comments. I won't try to disguise them as questions. We really have this fuzzy set of distinctions between standards development organizations and profiler enforcer organizations, and maybe a better way would be to say that there's a continuum between standards developers, profilers, and enforcers, three different kinds of organizations. If we look at the current NHIN Direct operations, for example, it's more of a profiler. That is, it didn't really define the standards. It decided how to pick among standards and sort of created the interfaces between the different kinds of standards.

Arguably, IHE is a profiler, and HITSP is a profiler, and the good, the real plus I see, one of the plusses in terms of the NIEM approach is that it can solve some of the big problems profiler organizations have had, such as not being able to create a coherent publication. It can only do that though if it acquires the right to an intellectual property from SDOs as part of that contract that you're working on. It has to have the ability to create derivative works on its own.

If you have the spectrum from SDO to profiler to certifier, you have sort of a triangle pointing the other way about the length of time it takes for work that is started there to become actually practical a means for health information exchange, and that's where, as you pointed out, Doug, we have this tremendous amount of time pressure on making decisions, recognizing that frankly from the start of an idea for a new standard, to it being practical for large-scale implementations. Unless it's a pretty trivial topic, we're talking about a minimum of five years. So I think there needs to be some sort of visioning process as well that is looking downstream for standards that we will need when there is time to actually use the benefits of an SDO consensus process to get a broad take on what the requirements are and what the possible solutions are.

John Halamka – Harvard Medical School – Chief Information Officer
Doug, any comments?

Doug Fridsma – ONC
No. I think I like the distinction that you've made between SDO profiler and enforcer. And I think trying to sort of meet our legislative requirements with standards development and to be able to support meaningful use, and to be able to balance that with making sure that we've got engagement from all of the various participants I think is one of the motivations and one of the reasons why I think we're trying to get something together in this standards and interoperability framework.

I will say one thing that is an unresolved issue, and I think this may be something that this committee can provide some input on is the issue that was raised about intellectual property and engagement with the standards development organization because clearly that is a limitation in terms of how we all work together with this and that if solving problems requires multiple different groups to be able to come together and bring their expertise to the table so that we have a comprehensive package that is useful to the implementers and to the folks that are trying to meet meaningful use, I think it will be important for us to get a way of a engaging the SDOs and making sure that we have a comprehensive policy, if you will, for how to engage the SDOs so that they can contribute to those packages and still be able to have business models and the like that are able to support the work that they do.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. Doug, if I could just repeat Rishel's rule of standards, when you change the consensus group, you change the consensus. And so we have all of these issues about if you take something that was developed by one group and then ask an SDO to endorse it, if that endorsement is meaningful, it's also going to change the standard. So you somehow need to create a collaboration process that the

standards, the SDOs are obligated to effectively put up or shut up and say, either we as an SDO endorse this and it becomes an active SDO, or the SDO doesn't play. It's going to take some kind of active leadership here to get beyond, you know, I talk about difficulties that HITSP had not out of disrespect for the people who struggled hard to do them, but nonetheless because of the struggles that they had.

John Halamka – Harvard Medical School – Chief Information Officer
Just two quick comments to Doug: You have included the SDOs in the S&I framework and in the NIEM process, and that is going to be actually an RFP you're going to recompete for some coordination there. One of the things I absolutely concur with what you said, it's so important to think about this intellectual property issue because one of the whole reasons why folks were confused by whether the C32 version 2.5 implementation guide included SNOMED and ICD-9 was because that inclusion was actually through indirection in C83, which was referenced in C32, and of course because of the fact that we can't license all of this stuff, we end up with artifacts pointing to artifacts pointing to artifacts. It would be wonderful to have crisp, clear artifacts that are all-inclusive and license intellectual property for general use. Other comments?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
John, I'm glad you said what that was because that's the underlying issue will be the business model and the financing of this continued maintenance of standards and whatever. And I think also knowing that there's still, you know, as I said, one of the issues for whether it's federal, state, or local entities as well is they generally get a path or an endorsement from their government entities to participate in ANSI accredited ideas because consensus based standards are generally not as partisan or exactly what they say, consensus based. But, yes, we should definitely address the business-financing model of this intellectual property and the continued development ….

I would just say also for those who are trying to help, as organizational providers or as government agencies, it can be or will be a bit bewildering on where to—all the various levels to assign resources to either provider input for here are our projects or either to supply bodies or to ask for funding. So I said we're looking very much forward to the next stage of this because it will certainly help us all get a context in which to do the work we all need to do. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
That … document will help a lot with that, and Doug's intent is to circulate it to us all when it gets to a stage where it's a bit more polished. Therefore, we'll have input into how all this interacts and how we interact with it.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
For those of us who have worked on years of integration, we love complexity, just like Wes Rishel loves complexity.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It's been a good living.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
But we definitely need some help to always communicating through leadership and decision-makers in something simpler.

John Halamka – Harvard Medical School – Chief Information Officer
Other comments that folks have on Doug's presentation?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. I made this point many times in the past, but I'm going to make it again, and I'm going to suggest that it's time to operationalize it. Many times I've talked to sort of the interplay between policy and technology and why, in the formation of standards and implementation guides or what have you, that policy really needs to be there in a visible and required way. My sense now is that because we've made some progress with the tiger team recommendations for information exchange, and because the ONC framework is kind of in place, that those policy requirements need to actually get to be a part of the way you are contracting for some of this work to be done. In other words, it's okay to say privacy and security on slide ten is an element here that we're working on.

But I think it really needs to be integrated into the approach of the framework in a very operational way. And I think it's timely to start thinking about ways to do that. Interoperability and harmonization also applies to policy, and I would hate to see us get into a situation where the technology standards or the use cases or the implementation guides have to be sort of reworked or the policy objectives can't be fulfilled because the technical requirements were kind of developed out of synch. And I know we tend to parse our work into policy and technology, but from my perspective, listening to this today, knowing what contracts are out, it's … moment to start to integrate these in an operational way.

The second point I want to maker is that just as you've said that this is a platform for collaboration and innovation, I would argue it should be a platform for innovation and collaboration on some of the policy objectives that need to be fulfilled by technology. So the tiger team … recommendations on consent, granular technology for consent and other things that really could be incorporated into this framework as a way to advance the policy objectives as well using technology. And I would just hate to see this so siloed that these are viewed as two separate areas or two separate strands of work and not brought together in a really robust and meaningful way.

Doug Fridsma – ONC
Carol, I think you're absolutely right, and we do need to make sure that we've got a close coordination with policy and the technology. Let me give you just an example of one of the challenges that I have, and I think one of the things that we're trying to achieve on the technology side that may require us to make sure that we don't have an impedance mismatch between policy and technology. So if our goal within the sort of standards and interoperability framework is to have the ability to have data and service descriptions be reusable across multiple use cases, so we have a granularity in the data elements that we describe and a granularity in the services, and we try to take those things and those Lego's, and create building blocks of that then can supply use cases.

It's important then that our policy work also thinks about things in kind of modular use case driven approaches within a larger framework. And so I certainly know that there's been work within the NHIN Exchange to develop the DURSA, which is a large, multiparty agreement. That agreement, if we have policies that are sort of one size fits all, but we have standards and services that are meant to be sort of modular and reused, we start to get into this sort of impedance mismatch, if you will, between policy and technology, and we have trouble doing exactly what you say, which is to make sure that there's this very close coordination within the team. So I would….

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, Doug. I don't think the policy right now gets in the way of a modular approach. In fact, I think … support it, and that the platform that you have for collaboration is a wonderful place to have it tested. But I just want to be clear about what I'm urging you to do, which is to not say that the technology and policy needs to be coordinated, but rather to say these are the policies that the technology that we're developing, or the standards that we're specifying, or the implementation guides that we're writing, these

are the policies that they have to fulfill. I worry if you don't do that, the policy work is kind of an academic exercise at best case, and at worst case it kind of gets at, the technical approach will have to get sort of rethought in the context of the policy down the road, which is also not an ideal outcome.

I agree that there's an interplay that is in both directions, but I just want to be clear that because the NHIN Direct work is happening on one front, and the policy committee and the tiger team are happening on another front that this is the moment because the tiger team is focused on stage one of meaningful use and information exchange, and because you guys are doing these contracts now to develop some of these specifications and the technical models. It has to be informed by at least a basic rubric of requirements.

The other thing I'll say is as you look at this platform for innovation on the technical front, you should look at it as a platform for innovation on the policy front. And the kind of hard problems and challenges that you mentioned technically can also be solved from a policy perspective by bringing those challenges to the same innovation platform and finding ways to solve them as opposed to sort of two streams at different paces, and then every now and then there's kind of a check in, and some will say, this won't work with what we're doing. There's a real membrane here that needs to be developed, and the requirement from the policy perspective has to be incorporated now into the contractual and ONC sponsored … or I worry that it may not come together.

John Halamka – Harvard Medical School – Chief Information Officer
Very valuable input, and one assumes, Doug, that the policies would be integrated in, in the use case activity at the very least, and one hopes multiple other checkpoints in the process.

Doug Fridsma – ONC
Sure. We've defined the Nationwide Health Information Network as the data standard services and policies to support information exchange. And so we need to figure out a way to make sure that that happens, and I think you're right, John, that it will likely happen at the beginning of the process through the use cases. And I think there is, you know, we just need to make sure that we are vigilant about that.

John Halamka – Harvard Medical School – Chief Information Officer
Any other closing comments before we move on to Jamie's vocabulary discussion?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Doug, one of the contracts was for reference implementation, and I'm curious. It's an implementation of what? Is it of the tools or of actual exchange services or some combination?

Doug Fridsma – ONC
It's meant to be of a specification that come out of the standards and interoperability framework. I can give you a concrete example, and that is, the Nationwide Health Information Network has a series of specifications that describes the data and the services for using NHIN and NHIN Exchange to provide that kind of exchange. We have FHA Connect, which is a tool and a piece of software that many people are using to help support exchanges in the NHIN specifications. But Connect, in and of itself, has made particular choices when it comes to optionality and some of the specifications.

That means that although Connect is an instance of the specification, it may or may not be considered a reference implementation because they've chosen to, for example, implement synchronous communications whereby the specifications talk about both synchronous and asynchronous communications. The goal here is to really have a one-to-one correspondence between the

specifications that we have for the nationwide health information network and for meaningful use, and have a corresponding piece of software or code that actually implements that.

John Halamka – Harvard Medical School – Chief Information Officer
Very good.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That sounds like an immense amount of software.

Doug Fridsma – ONC
I think that the rationale or the hope is that the reference implementation will, first of all, leverage much of the work that's been done in the past and make sure that we've identified from existing code those pieces that are part of that reference implementation. The goal is not to produce production level code that people could necessarily download directly, but to make sure that we've tested our implementation specifications and have gone through that particular exercise. Remember, we've got some open source communities that we have within the Connect project, and we're examining whether or not we can use similar mechanisms to help us with some of the work on the reference implementation following a model that has been successful with NHIN Direct and some of the open source communities around Connect.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Some of these questions people have brought up are really valid considerations. Have you established milestones and metrics for actually measuring and tweaking the process along the way?

Doug Fridsma – ONC
That's one of the first charges of the various folks that are working on the contracts is to essentially establish metrics, milestones, and risks so that we have the ability to track progress through this, and trying to integrate a lot of the work into the ongoing kind of operations within the Office of the National Coordinator. And so those things are all part of what we want to try to do with this work. Most of the contracts, as I said, have only really been awarded within the last three weeks, so there's lots of room for us to be able to take feedback and suggestions, recommendations, and sort of included in the work that's just beginning.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Those are metrics and milestones for the overall NIEMs process or for each of these …?

Doug Fridsma – ONC
Well, it's both of those. I mean, obviously the lower level metrics for each of the contracts needs to fit into the overall goals that we have for meaningful use. There needs to be a rolling up of those metrics to make sure that they're satisfying the overall objectives of the office.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much, everybody. We should move on to Jamie to get to our final two presentations, vocabulary taskforce and implementation workgroup update and, of course, public comment. Doug, thanks very, very much, and I look forward to … and further work and discussion on this because we all know there's going to be a lot of work ahead, but it provides a very powerful foundation.

Jamie, tell us about our upcoming vocabulary taskforce testimony on September 1st and 2nd at the ever popular Holiday Inn Capitol.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. Thank you. Well, if we could advance the slides, I think there's a slide that shows the workgroup members, the taskforce members, and then just one that has some information about the upcoming hearings. Just to cast your minds back, back in March, we held a public hearing on questions about national governance of terminologies, value sets, and subsets related to meaningful use, as a result of which we ended up making recommendations out of the taskforce, considered by the full committee that later were forwarded on to the national coordinator.

One of the themes that came out of that was a desire for one stop shopping to make it easy for implementers, both EHR vendors and actual users and clinicians to have access to and to use the required vocabularies, value sets, and subsets. And so the overall framing of this hearing, we actually have a day and a half of hearings coming up this week. Of course, timing is everything, and it would be great if we had just had the hearings, and I could report out on them. But I'm just going to say what's in it.

The gist of it is that we want to get input and understand what would constitute the right set of requirements for vocabulary infrastructure that would provide an ideal one-stop-shop, and which of the requirements would have the highest priority for achieving meaningful use. And so we have a list of questions that went out to our panelists. The overall questions, first, are basically what do you think a one-stop-shop means? What are the overall requirements for centralized infrastructure to implement one stop shopping for obtaining value sets, subsets, and vocabularies for meaningful use? And then, within that, which of the requirements or functionalities are urgent? What should come first? What would be a staged approach to get to the ideal end state over time?

Then we also have a series of detailed questions that our panelists will be addressing having to do with their experience, and we have a very broad set of panelists. We have currently 23 witnesses organized into these four sets. First we hear from the value set developers, and so that includes – the value set developers includes the AMA, the National Quality Forum, standards organizations HL-7 and X12. It includes CDISC and the CDC. Then we move into our second panel, which is really end users focused primarily on clinicians and hospitals and academic medical centers, which includes some of the taskforce members: Intermountain Healthcare, Mayo Clinic, Kaiser Permanente, also Partners Healthcare, and Columbia University, and University of Minnesota.

But then we hear from EHR vendors representing the spectrum of EHR vendors. Then finally, both as a reactor panel and to get their fundamental input on the questions, we hear from quite a variety of vendors, developers, and implementers of terminology services, both commercial and government sector, who are doing this today. So that includes the CaBIG and the National Library of Medicine, but it also includes 3M, Intelligent Medical Objects, SAIC, Apelon, and the Mayo Clinic. And so that's the structure of our agenda.

Now one problem that we had doing this at the end of August when a lot of people are on vacation is we did have a couple of last minute dropouts. In fact, just today we heard that the Canada Health Info Way folks would not be coming down to tell us about their experience. But we still have, as I said, 23 witnesses with whom we'll discuss all these requirements, and I think they do represent a very good cross section, a good cross setting set of stakeholders across the entire continuum. So that's our plan, and I'd love to take input and comments on it.

John Halamka – Harvard Medical School – Chief Information Officer
Questions?

W

Jamie, I don't think you have enough people on those panels yet. It looks like a very full agenda, even for the folks that you do have. I think it's been a Yeoman's effort to get all those folks. It looks very good.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
They're going to need to be as coordinated as Paul and Deven were in their presentation in order to get it all done.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, I think Betsy Humphreys and I will have to get out our whips and whistles to keep them in line.

John Halamka – Harvard Medical School – Chief Information Officer
Well, if there are no questions, we certainly look forward to the reports of the outcome of all of the testimony in our September … standards committee.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Now I do have one other thing while I have the floor for the clinical operations workgroup, of which the vocabulary group is a subset. Now is Aneesh still on the call, Aneesh Chopra? Well, I've heard from Aneesh, and we've talked a couple times in the last couple of weeks about the need to get better understanding and to get public input and testimony on standards for remote sensor data in EHRs. This is obviously a different topic, not for the vocabulary group, but for the clinical operations workgroup itself, the parent.

Examples of this would be collecting data on vitals in both hospital and clinical settings, but also remote sensor data for home and other remote settings. And so I just wanted to let everybody know, we will be setting up a meeting of the clinical operations workgroup to plan that hearing, and that'll proceed in the future, and so we'll come back to this group obviously from the clinical operations workgroup on that. But I just wanted to let folks know that we will be essentially restarting that clinical operations workgroup, which has been on hiatus, to start to structure a hearing to get testimony on this question.

John Halamka – Harvard Medical School – Chief Information Officer
Jamie, of course, there's been substantial harmonization work that's been done by Continua and IEG, IEEE, and I'm sure we'll have many interested parties from the community. Given especially the fact that new consumer devices are entering into the marketplace, this is very timely.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, everybody. Now let's move on to the implementation workgroup update. Judy and Liz.

Judy Murphy – Aurora Healthcare – Vice President of Applications
If you liked Jamie's short report, you're really going to like ours because we are also in transition. So if you go to the next slide, you can see that we are reworking our member list, and infusing it with some new faces. The new names actually have the word —new" after them. But we're kind of expanding so that we pull in some additional folks that have implementation experience that will be able to inform us related to our charge ahead.

If you go to the next slide, we have rewritten our broad charge, and we intend to dive down with some more specifics after our first meeting of this new group. But the broad charge to bring forward real world

implementation experience into the HIT Standards Committee recommendations with special emphasis on strategies to accelerate the adoption of proposed standards or mitigate barriers if any.

We have not had a meeting since our last meeting. It is scheduled for September 15th. We'll be doing an orientation to the new members in the beginning of the meeting and then diving into the detail of pulling together what we think our charge at a more specific level needs to be. Anything to add, Liz?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I don't think so except to thank all the members that have agreed to continue, and I think we've chosen a very broad group. We'd like to have input if you think we've missed someone.

John Halamka – Harvard Medical School – Chief Information Officer
Any comments? Not a controversial report. This is good.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Especially for the last one, which is great.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I was going to say, yes, we'll have to see how it goes next time, Judy.

John Halamka – Harvard Medical School – Chief Information Officer
Great. A very, very good discussion of many, many issues today. At this point, John Perlin, I think we are ready for public comment.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think we are. Let me add my thanks to yours to the group, a very robust discussion, and particularly appreciate Doug Fridsma really providing an overview of framing of how we approach many of these issues going forward. Judy, are we ready to bring in the public?

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, we are. Operator, could you please open the line and see if we do have any public comments? Just a reminder while you're queuing up that your comments are limited to three minutes, and please identify your name and your organization. Operator, do we have anybody on the line?

Operator
Yes. We have a comment from David Tao.

David Tao – Siemens Health Services – Interoperability Champion
It's David Tao from Siemens. I appreciated Doug Fridsma's presentation. I did have a question, a comment, and I don't know if I can ask a question, but I'll ask it anyway about the ONOP document or CONOP that John Halamka referred to. It sounds like that was going to tie a lot of the pieces together of these various RFPs. My understanding was that it would explain both how the various pieces fit together and how the public and SDOs, vendors, and so forth can be engaged and participate in this S&I framework.

I guess my comment would be, I would like to know—and I think the public would like to know as soon as possible—when that document that ties it all together will actually be available … answer that question today, that would be great, but if not, that's my comment. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Doug, are you willing to forecast or give David some general guidance?

Doug Fridsma – ONC
I think you're absolutely right that the CONOPs will help us tie all of these pieces together. I think we have a document that we've been working on, and we're beginning to sort of circulate to see if there are pieces that are missing. We've been coordinating with some of the other organizations, particularly with some of the folks from NIEM to see that we've got a consistent view of the world, and we've also been working with some of the folks from HHS that have participated in the NIEM process as well.

I think there is likely going to be something out in the next few weeks. I suspect it will be at a level of detail that will be higher than most people are going to want. But in part before we lock down entirely that concept of operations, I think it will be important for us to have some thoughtful public input to make sure that we've got really the coordination strategies right. I think that's one of the key parts of this. And I think, until we have all of our contracts awarded, it's going to be difficult for us to really have that in its finalized version.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any other questions, Judy?

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, we have one more.

Operator
We do have another public comment … Steve Richard at EMD.

Steve Richard – EMD
Yes. I was told by Dr. Halamka last week on a HIMMS call that the public surveillance test procedure is being reworked. Is this correct? And if it is being reworked, does someone have the documentation for that?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let me give this one back to Doug. We talked about this morning in my introductory remarks that I've gone through every question and query and talked to ONC and CMS about what seem to be inconsistencies in the standards final rule. Those inconsistencies actually didn't exist, except for one. It appears that the syndromic surveillance implementation guide in the final rule is actually the wrong CDC document, and so, Doug, if you could make a comment.

Doug Fridsma – ONC
Yes, John. We've identified this as an issue and a problem. Part of what happens when you do rulemaking is that the standards or the documents that describe the standards are incorporated in the final rule by a reference. And so the documents that were incorporated by reference, and the documents that we received from the CDC were not sort of reflective of the standards that we really wanted to include.

We are currently working on trying to figure out the best strategy for fixing that particular problem. I don't have a timeframe for you just yet or a particulr approach. We need to make sure that we work very closely with our office of general counsel to do things correctly. But I guess the best I can say is stay tuned. We realize that there is an issue that needs to be addressed and that we are actively trying to figure out what office we have to fix this.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Other questions?

Judy Sparrow – Office of the National Coordinator – Executive Director
No, we have no more questions, John.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, Judy, anything else on your end in terms of updates or logical information?

Judy Sparrow – Office of the National Coordinator – Executive Director
No, I think just the next meeting, we'll be back together again in Washington on September 21st.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I'm always impressed with people's ability to mentally attend through a long virtual meeting, and want to thank everybody for your participation and excellent discussion. And, as always, we appreciate the public input into this process. John Halamka, any closing comments …?

John Halamka – Harvard Medical School – Chief Information Officer
All I can hope is that Labor Day is actually going to mark the beginning of our vacation time because, just as ONC has been the office of no Christmas, it was the office of no summer, so I wanted to thank everybody at ONC and on the committee for all their hard work. It's really remarkable and let us hope that as we move forward to healthcare reform, stage two and stage three, that this becomes a polishing exercise and that much of the hard work that we have built in the last year is a foundation so that you can get your lives back. Thanks so much for all you do.

Jonathan Perlin – Hospital Corporation of America – CMO & President
With that, I think that's a terrific close. I wish I could get a sense that the cadence would slow down, but I think it was likely to maintain. So many thanks to all for what you've done, but keep the energy level up, much more to do. Thanks, ONC, John Halamka, and all members of the committees and public. We stand adjourned.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you.

Public Comment Received During the Meeting

1. Dr. Halamka made a comment in a HIMSS conference call that the Test Procedure for MU Syndromic Surveillance is being reworked. If so is the documentation out for this?
* (Private response removed from transcript)

2. ONC will need to coordinate 11 different contracts. How will they do so and enable coordination between them without becoming a bottleneck?

4. Re Healthcare extensions to NIEM: The definition of the data objects for NIEM will be the largest issue. NHIN will likely be best as an extension on top of NIEM, similar to jxdm. Definition of these associations and data elements are key. An advantage is that regional exchanges can extend the standard, and those extensions can be rolled into the larger standard if it proves to be valuable to everyone.

5. Has he mentioned the changes to MU Syndromic Surveillance Test Procedure?

8. Re: Recommendation 3.2 & the business rules within NIEM: Typically, NIEM is used to express the data elements and the associations between them. Some business rules can be inferred and enforced in the xsd at the data level, but higher-level rules are typically enforced in the applications. Some of the information is contained in the NIEM IEPDs.

9. Based on what we've seen with NIEM in the Public Safety sector, the data is likely there. The standardized codes will have to be translated/mapped during the XML generation to conform to the NIEM-like standard.